

Ankle Fracture Management System and FibuLock[®] Fibular Nail

Distal Extremities





EDUCATE. CHALLENGE. INSPIRE.

Arthrex Customer Engagement™ Program



Introduction ECI Playbook

Welcome to the Ankle Fracture Management and FibuLock[®] Fibular Nail 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 style 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

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Coach's Corner

A Message From Arthrex President and Founder

Arthrex offers the most comprehensive solutions for ankle fractures. Built on the clinical success of our Syndesmosis TightRope® implant, our Ankle Fracture Management System and Titanium Ankle Fracture System have quickly gained market share. Surgeons have also enjoyed the breadth and depth of these plate and screw offerings as well as our expertise and products in treating the other soft-tissue injuries of the ankle (AITFL, deltoid, etc).

In 2017, Arthrex acquired the FibuLock® fibular nail, a cutting-edge, minimally invasive solution for distal fibula fractures. Through a minimal incision, the FibuLock nail is able to stabilize the fracture during healing and provides stable fixation to restore length, alignment, and rotation. This product is aligned with our demonstrated success of providing minimally invasive surgical options.

The FibuLock drop-in caddies allow us to continue to provide the most complete ankle fracture solutions on the market and to deliver value to the accounts, surgeons, and patients in a single set. With over 250,000³ operative ankle fractures annually¹, our first-in-class products, and your continued expertise, you are positioned to dominate the market for years to come.

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Reinhold Schmieding | President and Founder





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Table of Contents

latva du ati a a	2
	2
Coach's Corner	3
Approach	5
Product Background and Rationale	5
Market Overview	6
Targeting	7
Primary Target Customer	9
Interview	10
Craft Compelling Questions	10
Demonstrate	13
Anatomy/Pathology	13
Introducing the Product	14
Key Features and Benefits	16
Video: The Perfect Demo	22
Surgical Technique	23
Additional Applications	23
Surgical Technique – FibuLock® Fibular Nail	24
Validate	25
Related Science	25
Competition	26
Negotiate	33
Clinical Objections	33
Nonclinical Objections	34
Close	37
Closing Question Examples	37
Appendix	38
Sales Tools	38
Ordering Information	39
References	40

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.



For further information, see the ECI Reference Guide.

Product Background and Rationale

Fueled by a commitment to Helping Surgeons Treat Their Patients Better™, the DEX team consistently develops innovative products that will open new opportunities for you to grow your business. Recently, we released the new Syndesmosis TightRope[®] XP implant system that simplifies our clinically proven knotless syndesmotic fixation system by eliminating the medial incision. In conjunction with this release, we would like to refocus on the Ankle Fracture Management System, which was purposefully designed to accommodate the TightRope button and its preparation. Using any other company's plate may compromise the safety and effectiveness of the Syndesmosis TightRope implant system.

Originally released in 2009, the Ankle Fracture Management System has undergone a few revisions and improvements and it is now the most comprehensive system available for surgeons to address ankle fractures. Most ankle fractures are not considered "hot trauma" and will be scheduled for the operating room or surgery center ahead of time. They are typically moderate- to lowlevel in difficulty and are therefore a great way for you to enter the plates and screws arena. Almost any orthopedic surgeon and podiatrist you are currently working with will probably be performing these types of procedures. To better accommodate all surgeon preferences, the locking third tubular, locking straight, and locking distal fibula plates are now available in titanium with the option of variable-angle screws distally.

Appendix

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Appendix

Product Background and Rationale (Cont.)

The Arthrex Ankle Fracture Management System has further expanded its comprehensive offering with the addition of the FibuLock® fibular nail. This minimally invasive solution to ankle fracture fixation satisfies surgeons' primary operative objective of restoration of anatomic length, alignment, and rotation of the fibula but through a smaller incision, which may help decrease wound complications. Compared to other intramedullary fibular fixation methods, the FibuLock fibular nail allows the surgeon to achieve both proximal and distal fixation along with syndesmotic fixation using the Tightrope[®] XP implant. The FibuLock instrumentation caddy can be added to your current Ankle Fracture Management System so you can be ready for these cases in a moment's notice.

Market Overview

Ankle fractures are one of the most common orthopedic fractures encountered by health care providers.²

- Over 600,000 occur per year³
- Treated either nonoperatively or operatively depending on the fracture pattern, soft-tissue condition, and level of displacement
- 33% of all ankle fractures are considered operative: ≈200,000 per year¹

- ASP ankle construct in 2016 was \$1450⁴ → potential market of \$290 million!
- Market growth due to an active, older population of "baby boomers"⁵

This segment offers enormous potential for new business for you as an Arthrex Technology Consultant. Using our dominant position and strong relationships in sports medicine and softtissue foot and ankle products, we can gain new business in this large market.



Close

Approach Targeting

Sports Medicine/General Orthopedic Surgeons

First and foremost, Arthrex is a leader in the sports medicine world. Therefore, you should use these strong existing relationships to gain new business. Your doctors are familiar with you and your service, and the hardest part may be just asking for the business.

An ideal target would be a sports or general orthopedist who gets ankle fractures through his/her office or takes calls at the hospital. Be confident that our offering is better than our competitors' and contained in just one tray. We will go into product detail later in this playbook. Exclusive vendor contracts are often discussed as a roadblock, but we can carve out an exception due to the unique features of our set, such as having one comprehensive tray, posterior fibula plates and hook plates, and approved use with the Syndesmosis TightRope[®] implant.

Traumatologists

This stakeholder controls the largest number of procedures, and should be targeted and not ignored. While many traumatologists identify Arthrex as a "sports company," our track record with the TightRope implant, all-in-one Ankle Fracture Set, and innovative products like the FibuLock[®] fibular nail and FiberTape[®] cerclage have captured their attention. Because trauma surgeons are very comfortable with intramedullary nail techniques, they are a great target for demoing the FibuLock nail. Innovation has been lacking within the trauma community for years; with superior relationship skills, consistency, and dependability, you can capture significant business. Communicating the cost savings of the all-in-one system and consistent availability will build your track record. Focus on the advantages of the TightRope implant, 2.7 mm cortical screws, and the availability of hook plates and posterior plates in an all-in-one set. At the 2017 OTA Meeting, Syndesmosis TightRope implant with our Ankle Fracture System was a highlight paper.

Todd Oliver, MD, a fellowship-trained traumatologist, was one of the main designing surgeons of the system. Additionally, trauma surgeon Mark J. Gage, MD, from Duke University, will provide his perspective on the system later in the playbook. For customers concerned about costs, you can position the Syndesmosis TightRope implant and ankle fracture plates together for their younger, insured trauma or sports injury patients.

Foot and Ankle Surgeons

Foot and ankle fellowship-trained surgeons will appreciate the breadth of implants offered in the set. With the drop-in posterior plate caddy, the set can provide everything required to perform either a lateral or posterior approach depending on the fracture pattern and the surgeon's philosophy.

The set was also designed with input from fellowship-trained foot and ankle surgeons such as Jorge I. Acevedo, MD.

Podiatrists

Arthrex has continually supported podiatrists, including being a platinum sponsor of the American College of Foot and Ankle Surgeons (ACFAS). Almost all podiatrists will be treating ankle fractures, although volume will vary depending on your region and the local institutions' referral arrangements. Some hospital emergency rooms send ankle fractures to the orthopedic trauma service, while others send them to the podiatry service. As with the other targets, discuss the advantages of the Syndesmosis TightRope implant and the breadth of implants included in one tray.

Approach Targeting (Cont.)

Positioning FibuLock® Fibular Nail

- Focus on all surgeons using competitive ankle fracture systems
- Position the FibuLock nail as the next generation of ankle fracture repair for surgeons currently using our Ankle Fracture Management System
- Approach trauma surgeons using competitive ankle fracture systems who commonly perform the following:
- Definitive fibular fixation at same time of ex fix placement for pilon fractures
- ORIF of highly comminuted distal fibular fractures
- Nailing of long bones for ORIF

Targeting for FibuLock Fibular Nail

Effective targeting is critical for the FibuLock fibular nail because surgeons tend to be protective of their current ankle ORIF protocols. They often do not consider the advantages of a soft-tissue—sparing approach to ankle ORIF, despite the fact that ALL orthopedic surgeons train extensively on nailing other long bones in the body.

Biggest Competitive Ankle Fx/FibuLock Targets

- Stryker
- Depuy Synthes
- Smith & Nephew
- Paragon 28
- Acumed
- Wright Medical
- Zimmer Biomet

Nailing has long been a proven approach to achieve and maintain anatomic reduction of fractures while preserving vascularity to the bone that is so critical to healing. ORIF through nailing also minimizes the incisions needed to adequately reduce and fixate fractures, resulting in fewer wound complications and infections.

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Negotiate

Appendix

Approach

Primary Target Customer

A Great Target



- Surgeons using competitive ankle fracture plating systems
- Surgeons using TightRope[®] XP implants for syndesmosis injuries
- Surgeons using competitive fibular nails
- Trauma surgeons nailing long bones

A Great Target

Surgeons currently using competitive ankle fracture systems are great targets for the Ankle Fracture Management System and FibuLock fibular nail. This is hands-down the most comprehensive system on the market, and the FibuLock nail further differentiates the offering. Surgeons now have a fantastic solution to treating their common ankle fractures with a minimally invasive approach. Base your initial conversation(s) on surgeons' high-risk patients (patients with severely comminuted distal fibula fractures, etc). This is where the FibuLock fibular nail can have the most immediate impact on the surgeon's practice and give them the confidence to expand their indications for the FibuLock nail. Those surgeons using our TightRope implant for syndesmotic injuries should be using our Ankle Fracture Management System as well. Our plates are recessed to accommodate the TightRope button, which allows them to sit flush in the plate, reducing the overall profile and minimizing the risk of the plate cutting the suture. Competitive plates are not made to accommodate the TightRope implant.

Surgeons using our ankle Fx plates, but need to

be introduced to the FibuLock[®] nail

A Good Target

A Good Target

This surgeon is already using the Ankle Fracture Management System, but has not yet been introduced to the FibuLock fibular nail. Show them the advantages of a minimally invasive approach, especially in their high-risk patients. Length and rotational stability are still attainable, while maintaining vascularity and reducing the risk of infection.

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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 Ankle Fracture Management System with the FibuLock[®] fibular nail to your customer or converting them from another product, **you need to uncover their needs and challenges** to most effectively present how this system is the right solution. Following the ECI interview process, you will be able to identify strategies that best differentiate the Ankle Fracture Management System with the FibuLock fibular nail from competitive products and upgrade the surgeon to the latest technology Arthrex has to offer.

Current Situation

 Have you heard of the Syndesmosis TightRope[®] implant? (The goal is to start a discussion about the technology and the plate hole design, which accommodates the TightRope button. Please refer to the TightRope Implant Playbook for a more in-depth discussion on this topic.)

- What approach do you typically use for fixing the fibula during ankle fractures? (The goal is to determine whether they ever use the posterior approach and, if so, what type of plate they are using. Emphasize that the posterior plates can be included inside the ankle fracture tray.)
- How do you typically address very distal fibula or medial mal fractures? (The goal is to set up discussion on our hook plates. Emphasize that everything is in the tray.)
- What sets do you typically need for an ankle fracture case? (The goal is to discuss the advantages of the all-in-one system.)



- How do you manage incisions in challenging pilon fractures with concern for appropriate skin bridge? (The goal is to discuss the advantages of a smaller incision on the fibula allow the surgeon more options when addressing the tibia.)
- When treating high tib/fib fractures (tibial nailing), do you fix the fibula as well? Would you fix the fibula if you had an approach that only required a few small incisions versus a large spanning plate?
- What are your thoughts on using a minimally invasive approach for patients with challenging fracture blisters/soft tissues/concerns about making a large incision? (The goal is to discuss the advantages of a smaller incision on the fibula.)
- If you had a better technique for ankle fractures that preserved biology, how often would you use it? (The goal is to discuss how less swelling and less pain lead to accelerated mobility.)
- Are you currently nailing fractures for ORIF?

Desired Situation

- How important is compression to you in treating transverse, Weber A fractures?
- Would you benefit from having access to several plating options and cannulated screws on the same set?
- Are you open to exploring some new options for your ankle ORIF patients?
- How can treatment of ankle fractures in high-risk patients improve? What is the next step?
- If you had a better technique for ankle fractures that preserved biology, how often would you use it?
- How does your incision factor into your post-op rehab protocols for ankle fracture patients?

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Interview

Appendix

Negotiate

Interview

Craft Compelling Questions (Cont.)

Risk/Concerns

- Are you ever concerned with the limited plating/ fixation options in the current small fragment system you're using?
- Are you ever concerned about the prominence of the TightRope[®] button on your Synthes plates?
- Are you ever concerned with hardware prominence?
- Do you have concerns about applying nailing principles to ORIF of ankle fractures?
- Do you have concerns about wound complications associated with long lateral incisions for ankle fracture ORIF?
- What risks are associated with early rehab of ankle fracture patients?

Benefits/Rewards

- Do you see any benefit to your OR efficiency by having a single, comprehensive system for treating all ankle fracture types in your room for ankle fracture cases?
- If the improvement you mentioned could be made, how would this affect your patients' outcomes?
- Would intramedullary fixation reduce hardware prominence and the potential need for a second surgery to remove hardware for your patients?
- What benefits would you see in applying nailing principles to ORIF of ankle fractures?
- Would any of your patients benefit from the elimination of a large lateral incision in ankle ORIF?
- How might your rehab protocols change for ankle fracture patients if the lateral incision were eliminated?

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

The main bones that make up the ankle are the tibia, fibula, and talus. The medial, lateral, and posterior malleoli are bony prominences on the fibula and tibia (see illustration, right). An ankle fracture occurs when one or more of these malleoli breaks and can be caused a number of different ways, such as a slip or fall, sports injury, or high-energy trauma.



One way clinicians describe ankle fractures is by the number of malleoli involved: unimalleolar, bimalleolar, and trimalleolar.⁷ There are also two classifications that are generally used when describing ankle fractures: the Lauge-Hansen classification and the Danis-Weber classification.

The Lauge-Hansen classifies ankle fractures by the rotational mechanism of injury based on foot position at the time of the traumatic event (supination or pronation) and the direction of the deforming forces (abduction, adduction, or external rotation).⁸ A limitation of this system is that the mechanism is rarely truly known and is often speculated.⁹ The complete classification is shown below for reference.

Category	Stage			
Supination external rotation	1 Injury of the anterior inferior tibiofibular ligament			
	2 Oblique/spiral fracture of the distal fibula			
	3 Injury of the posterior inferior tibiofibular ligament or avulsion of the posterior malleolus			
	4 Medial malleolus fracture or injury to the deltoid ligament			
Supination adduction	1 Transverse fracture of the distal fibula			
	2 Vertical fracture of the medial malleolus			
Pronation external rotation	1 Medial malleolus fracture or injury to the deltoid ligament			
	2 Injury of the anterior inferior tibiofibular ligament			
	3 Oblique/spiral fracture of the fibula proximal to the tibial plafond			
	4 Injury of the posterior inferior tibiofibular ligament or avulsion of the posterior mallelous			
Pronation abduction	1 Medial malleolus fracture or injury to the deltoid ligament			
	2 Injury of the anterior inferior tibiofibular ligament			
	3 Transverse or comminuted fracture of the fibula proximal to the tibial plafond			

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Negotiate

Validate

Demonstrate

Anatomy/Pathology (Cont.)

The Danis-Weber classification, more commonly referred to as just the Weber classification, categorizes ankle fractures by the position of the distal fibular fracture in relation to the syndesmosis. This is a simpler system that can be assessed radiographically.⁷

Weber A – Infrasyndesmotic (generally not associated with ankle instability)

Weber B – Transsyndesmotic (have the TightRope[®] implant available) B1: isolated

- B2: associated with a medial lesion (malleolus or ligament)
- B3: associated with a medial lesion and fracture of the posterolateral tibia
- Weber C Suprasyndesmotic (have the TightRope implant available) C1: diaphyseal fracture of the fibula, simple
 - C2: diaphyseal fracture of the fibula, complex
 - C3: proximal fracture of the fibula

Fracture above the syndesmosis resulting from external rotation or abduction forces that also disrupt the syndesmosis Usually associated with an injury to the medial side

Introducing the Product

The Ankle Fracture Management System (AR-8943S) provides all the instruments and implants required for the majority of ankle fracture cases you will encounter. This single system contains 2.7 mm locking, 3.0 mm cancellous, 3.5 mm cortical and locking, 4.0 mm cancellous, and 4.0 mm cannulated screws (short and long thread), and 5 standard plates: locking third tubular, locking straight, locking distal fibula, locking lateral hook, and locking medial hook plates.

There are also options for a drop-in caddy of posterior and posterolateral fibula plates or 2.7 mm cortical screws. This is far and above more comprehensive than the offerings by Synthes and Stryker who are the market leaders. Neither company makes any specific posterior plates for the fibula for use in the posterolateral approach, which has seen a resurgence in recent years. Due to Arthrex's early focus on foot and ankle, we have been able to develop the best solution for ankle fractures on the market. It is now up to you to take this business from our competitors!

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The FibuLock® fibular nail (AR-8973S) drops into the stainless steel Ankle Fracture Management System (AR-8943S). The nail was designed to restore appropriate length, alignment, and rotation of a stable ankle mortise, while using a softtissue-friendly, minimally invasive approach.

The FibuLock fibular nail remains the only nail with proximal and distal fixation and accepts the TightRope XP implant, which allows for treatment of almost any ankle fracture pattern.





Appendix

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Demonstrate

Introducing the Product

Value Proposition

The Arthrex Ankle Fracture Management System remains the most comprehensive ankle fracture system on the market. Surgeons can treat the full spectrum of ankle fracture pathologies, all with one system. The system is available in stainless steel and titanium so no matter a surgeon's metal preference, we can accommodate. With the addition of the FibuLock® fibular nail, surgeons now have an excellent minimally invasive approach to ankle fracture fixation that achieves length and rotational stability while preserving the soft tissues and maintaining the blood supply to the bone. When paired with TightRope[®] XP implant, the clinically proven gold standard for syndesmosis fixation, now even high-energy ankle fracture pathologies can be addressed with an "all-inside" approach.

Value Includes:

- Seven fibular plating options in one system
- Tissue-sparing option in the FibuLock fibular nail
- Longer sterile plate options
- Available in stainless steel or titanium
- Comprehensive screw options, including 4 mm cannulated
- Designed for use with the TightRope XP implant
- Well-trained, local representation
- Physician and patient medical education resources
- Made in the USA

Scrub Sink Pitch

The FibuLock fibular nail is an implant that allows for a soft-tissue–sparing, minimally invasive approach to ankle fracture fixation. While it is not the only fibular nail on the market, it is the only implant with the ability to achieve proximal fixation, through the use of "talons" that are activated after insertion. The nail accommodates multiplanar screws distally that lock in rotational stability. In addition, the FibuLock nail has the unique ability to accommodate syndesmotic fixation, including the TightRope XP implant, through the nail itself.

We feel strongly that the FibuLock fibular nail is an excellent option for high-risk patients who would benefit from a minimally invasive approach to prevent wound complications and preserve the vascularity that is so critical to bone healing. Even beyond this, we have seen the FibuLock nail become the implant of choice for ALL ankle fractures in many surgeons' practices. They begin to realize the simplicity of the system, sustained positive outcomes, and the potential for enhanced rehab protocols with the elimination of the lateral incision.

Approach

Validate

Appendix

Demonstrate

Key Features and Benefits

The Ankle Fracture Management System was designed from the ground up for use with the Syndesmosis TightRope® implant. The screw holes and contouring of the plates allow the lateral button to sit perfectly in the plate or adjacent to the plate. Additionally, the locking distal fibula plate has three holes at the level of the syndesmosis with 35° posterior-to-anterior cutouts to facilitate anatomic preparation and drilling for the Syndesmosis TightRope implant. If you have a doctor who believes in the TightRope implant, he/ she should be using Arthrex plates with it.





TightRope button sitting inside and adjacent to an Ankle Fracture Management System plate.

Aside from its advantages with the Syndesmosis TightRope implant, the Ankle Fracture Management System is an excellent stand-alone plate and screw set. It can address the majority of all ankle fracture cases using just one tray. There are five different plates and a variety of 2.7 mm, 3.0 mm, 3.5 mm, and 4.0 mm screws, including cannulated 4.0 mm screws for medial and posterior malleolar fractures. TightRope button in 1 of 3 holes with a 35° drill angle for the syndesmosis prep.

All of the clamps, K-wires, and benders needed are also included in the tray. Additionally, the trays can be customized for each user's individual needs. There is an optional drop-in caddy with two types of precontoured posterior fibular plates and another optional caddy with 2.7 mm cortical screws for those who prefer lagging with smaller 2.7 mm screws.



Posterolateral Fibula/Straight Plate Caddy (AR-8943C-PC-01) drops into existing Ankle Fracture Sets.





2.7 mm Screw Caddy (AR-8827C-10)

Demonstrate

Validate

Negotiate

Demonstrate

Key Features and Benefits (Cont.)

Locking Distal Fibula Plate



- Most popular precontoured plate in the system
- Surgeons love the fit and low profile of the plate: 1.2 mm distally/2.0 mm proximally
- 35° hole cutout for TightRope[®] drill bit in the 3 distal shaft holes
- Often used in Weber B fractures and some Weber A and C cases



Surgical tip – Distal screws are angled slightly superior and not directly perpendicular to the plate. The screws and drill towers can be forced into an incorrect orientation, but the screw heads won't lock into the plate properly.

Close

Demonstrate

Key Features and Benefits (Cont.)

Locking Third Tubular Plate



- Most used plate in the tray
- 1.5 mm thick
- Can use 3.5 mm cortical, 3.5 mm locking, and 4.0 mm cancellous screws
- Additional metal was added to the underside of the plate to increase the strength of the construct
- Often used in Weber B and C cases

Locking Straight Plate



- Similar in design to conventional recon plates
- Plates are cold-worked instead of annealed
- Traditional recon plates are annealed
- 2.3 mm thick
- Often used in Weber C cases with the Syndesmosis
 TightRope[®] implant and some Weber B fractures where
 more strength is needed than a third tubular plate











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Demonstrate

Key Features and Benefits (Cont.)

Locking Lateral Hook Plate





- Can compress with the hooks, compression slot, and/or a 4.0 mm screw
- Low-profile 1.5 mm distally/1.5 mm proximally thick
- Synthes and Stryker don't offer these plates
- Great for overcoming "trauma contracts"
- Often used for Weber A fractures and avulsion fractures

Locking Medial Hook Plate





- Can compress with the hooks, compression slot, and/or a 4.0 mm screw
- Low-profile 1.5 mm distally/1.5 mm proximally thick
- Synthes and Stryker don't offer these plates
- Great for overcoming "trauma contracts"
- Often used for very distal medial mal fractures and avulsion fractures

Note: Plate hooks will not sit flush because of the deltoid ligament.

Close

Approach

Approach

Demonstrate

Close

Demonstrate

Key Features and Benefits (Cont.)

Posterior and Posterolateral Plates (NOT STANDARD)





- Originally found in the Distal Tibia System
- Can be added to the Ankle Fracture System with AR-8943C-PC-01
- Posterolateral distal fibula plate is also called the posterolateral anatomic distal fibula plate
- Posterior distal fibula plate is also called the posterolateral distal fibula plate
- Posterolateral distal fibula plate = 1.0 mm distally/2.0 mm proximally thick
- Posterior distal fibula plate = 1.0 mm distally/1.5 mm proximally thick
- Design aids in fracture reduction
- Functions as an antiglide plate
- Biomechanically stronger
- Can lag screw through plate
- Same incision as when plating a posterior mal fracture
- Posterolateral plate has a hole and cutout for the Syndesmosis TightRope[®] implant

Demonstrate

Key Features and Benefits (Cont.)



FibuLock[®] Fibular Nail



- Soft-tissue—friendly, minimally invasive approach for fibula fractures
- Only system on the market with proximal fixation (talon) capabilities
- Achieves both proximal and distal fixation along with syndesmotic fixation when paired with TightRope[®] XP implant
- Multiplanar distal fixation allows for treatment of almost any ankle fracture; controls rotation
- Nail insertion outrigger can provide compression if needed and ensure syndesmosis fixation is parallel with the TightRope XP implant system (or 3.5 mm screws) angled posterior to anterior

Demonstrate

Video: The Perfect Demo



DS-252 FibuLock® Fibular Nail Demo

The FibuLock Sales Trainer DS Kit allows you to demo the FibuLock fibular nail in a surgeon's office or in a dry lab setting. The kits are also a great way for technology consultants to get hands-on experience before their first case while reviewing tips and pearls of the instrumentation

Demo kit includes:

- Custom fibular sawbone
- 1.6 mm guidewire
- 6.2 mm reamer
- 3.2 mm reamer
- 3.0 × 130 mm left FibuLock nail

The sawbone has been uniquely designed with a spongy fibular canal to make demonstration of the canal prep easy. The nail can be reused for multiple demos with surgeons or reps as long as the talons are deactivated after each use.

Other items needed for demo:

- Arthrex power
- Actuation driver
- FibuLock fibular nail instrument insert (AR-8973S), which includes the 2.7 mm screws

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ARTHEEX FIEULOCK 1127-48

Validate

Approach

Interview

Demonstrate

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Approach

Demonstrate

Validate

Demonstrate

Surgical Technique

The most common ankle fracture is a Weber B oblique fracture.

Treatment: lag screw and neutralization plate.

View AO technique here.

Posterolateral fibula plating: Surgeons who like to plate the fibula laterally will often comment that posterolateral plating causes peroneal tendon irritations. Surgeons who use a posterolateral technique commonly will say this is not the case if the plate is positioned above the superficial peroneal retinaculum (SPR). If your surgeon wants to use the new posterolateral plates but has that concern, have them use the SPR (plating just proximal) as a landmark to minimize peroneal tendon irritation.

Locking medial hook plate: The hooks in the plate were designed to grab the deltoid ligament so they may not sit directly in the medial mal. Some surgeons prefer to have the hooks in the bone, so we recommend predrilling the holes with a 2.0 mm or 2.5 mm drill to achieve this.

Additional Applications

Surgeons have used the plates in a variety of locations outside of the ankle as well.



Reconstruction plate used in the clavicle.





Demonstrate

Surgical Technique – FibuLock[®] Fibular Nail

FibuLock Fibular Nail Entry Point Tips

- Reduce the fracture first
- Initial view is frontal (mortise or A/P) to find the fibula tip
- Supinate the foot for easier access to the fibula tip
- Use alternating AP and lateral views to confirm placement
- Get the entry point first and then the proper trajectory
- Oscillating the entry wire prevents breaching of the cortex
- It is better to be slightly medial than lateral to avoid reaming out the lateral cortex in the next step
- Do not proceed with the case until the entry point and wire trajectory are correct!





FibuLock Fibular Nail

Lateral edge of the malleolar fossa

Fossa outline



Correct trajectory

Removal Tips



Remove the end cap and screws with a T15 driver.



Extract with the slap hammer.



Deactivate the talons. The talons will close during extraction.

Ordering Information

AR-8973RK; sterile

If you have the Sonoma removal kit (ST6900), note that this item is **NOT** sterile. You will need to drop it off to be sterilized before use.

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

 Minihane KP, Lee C, Ahn C, Zhang LQ, Merk BR. <u>Comparison of lateral locking plate and antiglide</u> plate for fixation of distal fibular fractures in osteoporotic bone: a biomechanical study. J Orthop Trauma. 2006;(8):562-566. doi:10.1097/01.bot.0000245684.96775.82.

FibuLock® Fibular Nail

- Walton DM, Adams SB, Parekh SG.
 Intramedullary fixation for fractures of the distal fibula. Foot Ankle Int. 2016;37(1):115-123. doi:10.1177/1071100715622392
 - This technique can lead to faster healing, accelerated rehab, and decreased hospital stays.
 - Can reduce the most common complications such as wound breakdown and infection.
- Goss DA Jr, Reb CW, Philbin TM. <u>Anatomic</u> <u>structures at risk when utilizing an</u> <u>intramedullary nail for distal fibular fractures: a</u> <u>cadaveric study.</u> *Foot Ankle Int.* 2017;38(8):916– 920. doi:10.1177/1071100717709572
 - Peroneal tendons and superficial peroneal nerve are at greatest risk; however, none were violated during 10 cadaveric fibular nail placements adhering to sound percutaneous surgical technique.

- Smith G, Mackenzie SP, Wallace RJ, Carter T, White TO. <u>Biomechanical comparison of</u> <u>intramedullary fibular nail versus plate and</u> <u>screw fixation.</u> *Foot Ankle Int.* 2017;38(12):1394-1399. doi:10.1177/1071100717731757
- 20 lower limbs (from 10 cadavers), one ankle randomly allocated to either fibular nail or 1/3 tubular plate and lag screws.
- Fibular nail was found to be superior to a standard lag screw and neutralization plate in torque to failure testing.
- Strongly corroborates the torque at failure data derived from mechanical testing in finding the nail has a superior construct to the plate.



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FibuLock Fibular Nail

Appendix

Validate

Competition

Synthes

- 2.7/3.5 mm Variable Angle LCP Ankle Trauma System
- Stainless steel
- Market leader for orthopedic trauma with a wide range of products
- Not focused on foot and ankle like us
- Common standard, but they don't have any TightRope[®] implant-like product and don't have fracture-specific plates.

Plate options:

- 2.7/3.5 mm LCP lateral distal fibula plate
- VA 2.7/3.5 mm lateral distal fibula plate
- Locking 1/3 tubular plates
- Multi-use hook plate but not fracture-specific

Sell against:

- High cost for their variable angle plates
- Hidden high costs in cannulated screws and drill bits
- Challenge accounts to analyze last 10 Synthes cases construct pricing
- Bulky size to accommodate the VAL
- No anatomical hook plates
- Same hook plate for lateral mal, medial mal, and olecranon
- Need multiple trays for all of the plates and cannulated screws
- Not designed for the Syndesmosis TightRope implant







Approach

Validate

Negotiate

Demonstrate

Validate

Competition (Cont.)

Stryker

VariAx® Distal Fibula Locking Plate System

- Titanium
- Very limited offering
- Most of their ankle fracture business is from contract conversions
- Reps don't lead with this product
- Set includes 4.0 cannulated screws
- No TightRope® implant-like option

PEARL - Titanium debris is created when inserting the screws and also when drilling with the 3.7 mm drill for the Syndesmosis TightRope implant because their screw holes are smaller.

Plate options:

- 3.5 mm VA fibula plate
- 3.5 mm locking straight plate
- 3.5 mm locking 1/3 tubular plate

"We had a surgeon yesterday removing a Stryker titanium ankle fracture plate and, while performing the removal, the screw heads broke off inside the plate."

- Mountain West Region

Sell against:

- VariAx nonlocking screws don't work well as lag screws because the screw pitch is not truly cortical but a hybrid
- Fibula plate is not side-specific and doesn't fit well
- Increased bone removal for 3.5 mm distal screws on the fibula plate
- Limited screw options, no 2.7 mm or 4.0 mm screws originally
- Stryker has recently added 2.7 mm locking screws to some of their trays.
- Screw heads are known to break off because of their reduced geometry and softer material (titanium)
- Not designed for the TightRope implant

Former Stryker Trauma Rep



screws from that set if I wanted a lag screw to get any bite."

"I always had to bring in a separate Ti small frag and use the cortical

Negotiate

Validate

Competition (Cont.)

Zimmer Biomet

A.L.P.S.® Distal Fibula Plating System

- Titanium
- Originally a Depuy plate that Zimmer Biomet acquired
- Variable angle locking available

Plate options:

- Anatomic fibula locking plate
- Fibula composite locking plate

Sell against:

- Plates are incredibly thick. The anatomic plate is 2.8 mm proximally and 2.3 mm distally
- No 1/3 tubular option, which is the most used plate for ankle fractures
- 2 different drivers needed: square driver and T15
- Square driver strips out easily
- Not designed for the TightRope® implant

Periarticular Locking Distal Lateral Fibula System

- Stainless steel: 22-13-5 grade
- Thin plate that fits well
- Variety of fixed angle 2.7 mm and 3.5 mm locking and nonlocking screws

Plate options:

- Only the distal fibula plate in this tray
- Zimmer has a separate small fragment tray with 3.5 mm ¹/₃ tubular, recon, and compression plates, available in nonlocking and locking

Sell against:

- Need to open multiple trays for more plate options and cannulated screw
- Can't measure off the locking towers for 2.7 mm screws
- Cumbersome instrumentation
- Not designed for the TightRope implant







Appendix

Competition (Cont.)

Paragon 28

Gorilla® Ankle Fracture Plating System

- Titanium system
- 2.7 mm, 3.5 mm, or 4.2 mm locking and nonlocking polyaxial screws
- All use a 2 mm drill bit for predrill
- Plates are 1.5 mm thick
- Tapered ends

Plate options:

- Anatomic fibula plates
- Straight fibula plates
- Medial malleolus plate
- Posterolateral fibula plates
- Posterolateral tibia plates
- Posteromedial tibia plates
- Trimalleolar fracture plates

Sell against:

- They charge a lot for their products
- Field reports that their screw heads are breaking off
- Tapered heads are not ideal for lagging fractures
- No hook plates
- Not designed for the TightRope® implant

N	ION-LOCKIN	1G		LOCKING		COMPRESSION
2.7	3.5	4.2	2.7	3.5	4.2	4.2
1-1	110	T	1		1	100
		县			1	1
K	4	44	2	3	R	
2	2	R	- X		1	22
X	4	44	2	8	36	1
2	2	R	- A		-	1
A.	*	*	2	32	SK.	
-P-		-	1	4	4	-

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Close

Validate

Competition (Cont.)

Acumed

Acumed Locking Ankle Plating System

- Titanium
- Fixed-angle locking and nonlocking screws

Plate options:

- Low-profile locking lateral fibula plates
- Lateral fibula plates
- Low-profile locking anterior tibia plates
- Low-profile locking medial tibia plates

Sell against:

- 2 different drivers needed: hex and hexalobe
- Not side-specific distal fibula plates
- No hook plates
- Not designed for the TightRope[®] implant





Appendix

Validate

Competition (Cont.)

Wright Medical Technology

ORTHOLOC 2

- Titanium
- Variable-angle locking and nonlocking screws

Plate options:

- Syndesmosis
- Lateral fibula (straight and offset)
- ∎ 1/3 tubular
- Hook
- Medial malleolar
- Posterior malleolar

Sell against:

- The fibula plate is too narrow distally so won't help to reduce distal comminuted fractures
- The fibula plate only has 2 hole options for syndesmotic fixation and doesn't sit very distal
- Offset plates won't consistently fit all patients and this part can't be bent
- 2 styles of hook plate have the same curvature, which requires bending to fit well
- No recon plate offered
- No posterior fibula plating options
- No 2.7 mm cortical screws in the tray



Syndesmosis



Lateral Fibula

1/3 Tubular

Hook



Posterior Malleolar

Validate Competition – FibuLock® Fibular Nail



	Νο	Sell By	Claimed
- acumed [®]	Proximal fixation TightRope® implant for syndesmosis Divergent screw fixation Anatomic – one side Poor instrumentation	Demo with instrumentation Nailing principles TightRope implant compatibility Your service	
<image/>	Proximal fixation TightRope implant for syndesmosis Divergent screw fixation 3 mm largest diameter	Representation? Nailing principles: proximal fixation Bail out; limited options	
	Proximal fixation TightRope implant for syndesmosis Low-profile screws—large screw Poor instrumentation	Demo with instrumentation Nailing principles: proximal fixation TightRope implant compatibility Your service	Oblique AP inter-frag screw Nailing principles: proximal fixation Bail out; no ankle plates

Approach

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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 Ankle Fracture Management System. It is your responsibility to clearly identify any objections about so you can address them with supporting evidence. Keep the discussion moving toward closing or gaining commitment to use the Ankle Fracture Management System.

Clinical Objections

Your system doesn't have variable-angle locking capabilities.

If they are not opposed to titanium plates, show them the Titanium Ankle Fracture Set, which has variableangle distal screws. If they want stainless steel plates, you can discuss how variable-angle screws have advantages in some situations but are not necessary for ankle fractures. The fibula is small and limited in space for screws. Fixed trajectory screws allow the most screws without concerns of screw interference.

I use the TightRope® implant in my existing non-Arthrex plates.

The TightRope implant was not designed for use with non-Arthrex plates. Using it with other plates can lead to adverse complications. For example:

Synthes

- Problem Lateral button has no "home" to sit in and can migrate.
- Complication The TightRope implant can lose
 tension and result in diastasis of the syndesmosis.

Stryker

- Problem Stryker screws have narrow, recessed heads so the button sits above the plate.
- Complication Same effects as a proud screw head.
 It can cause soft-tissue irritation over this area.

Smith & Nephew

- Problem The locking mechanism is a star-shaped hole. The edges of those stars can become sharp while drilling with the 3.7 mm drill bit, especially when drilling posterior to anterior.
- Complication These edges can cut or fray the FiberWire® suture, which may cause immediate or latent loss of syndesmotic fixation.¹⁰









The nail doesn't hold reduction.

In fact it does, but only with proper technique. To get proper reduction, you have to reduce the fracture and ream with it reduced for the nail to hold the reduction.

If you can't do a case percutaneously, then you might as well open and plate.

A 2 cm incision to make your reduction perfect is still better than a 10 cm incision for a plate. You can always slightly extend your percutaneous incision, but a plating incision is large to begin with.

You can't do a FibuLock implant on a comminuted ankle fracture.

These are some of the best cases for FibuLock implants. The nail can be used to span the fragments while maintaining the periosteum and keeping blood flow to the fracture.

The nail should help get the reduction.

This is a misunderstanding of nailing principles. You must always ream and prep the fracture in a reduced state if you want the nail to hold the reduced fracture. The nail will follow the path that was prepared for it.

Nonclinical Objections

Synthes lives on the shelf.

Surgeon support is critical here. Synthes does not have the options we have in one tray, nor does any other company for that matter. The surgeon and facility need to trust that you can handle their demand, whether that means keeping a tray permanently at the facility, or just making sure it is available for surgeons' weekend calls.

Your plates cost too much compared to my normal plates.

There is a common misconception that Arthrex is overpriced. Inquire as to why they are under that impression. Make sure that their comparisons are "apples to apples." Often facilities will compare cortical plates and screws to our locking options. We are cost-competitive the vast majority of the time. Make sure to differentiate our system from whichever competitor we are being compared to.

We have an approval process your system would need to go through.

We have a multitude of resources, including VAC packs, that can be supplied to facilities to aid in product approval. Be sure to ask for the surgeon's support during the approval process (eg, include the surgeon on initial approval request to facility). Interview

Nail Cost Effectiveness:

In 2015, Matthew Bradley, MD start using the FibuLock fibular nail for high-risk patients at SSM hospitals in St. Louis, MO.

To gauge whether the FibuLock nail was cost effective in comparison to traditional surgical plates, SSM cost accounting representatives analyzed Dr. Bradley's cases. After preliminary analysis, SSM was impressed by the cost effectiveness of the FibuLock nail, and now fully supports its use in Dr. Bradley's ankle fracture cases.

Here is a summary of the initial findings from the cost analysis:

		FibuLock Fibular Nail		Plates			
Variable	Cost Per Variable	Units	Costs	Units	Costs	Total FibuLock Savings	Notes
Suture packets used	\$40.00	1	\$40.00	3	\$120.00	\$80.00	FibuLock incisions are 80% smaller than plates and require less suture
Minute of OR time	\$100.00	20	\$2000.00	40	\$4000.00	\$2000.00	On average, plate surgeries require 20 more minutes of OR time to close incisions
Surgical tray sterilization	\$75.00	1	\$75.00	4	\$300.00	\$225.00	Plate surgeries require more trays for small fragment and screw options
						\$2305.00	

FibuLock Ankle Nail Economic Case Study Contributed by Matthew Bradley, MD

Postoperatively, SSM hospitals are most likely experiencing additional savings from using the FibuLock nail. There have been no postoperative infections or nail removals among my FibuLock nail patients since I started using the device 18 months ago. A recent study has shown a minimal 4% infection rate among a population of 439 plated patients adds an additional \$2300 to the cost of every ankle fracture patient's care.*

Furthermore, my patient satisfaction scores are much higher among FibuLock[®] nail patients. This is advantageous to the SSM hospital reputation as well as having a positive future impact on the reimbursement schedule.

*Avilucea FR, Greenberg SE, Grantham WJ, et al. The costs of operative complications for ankle fractures: a case control study. Adv Orthop. 2014;2014:709241. doi:10.1155/2014/709241



FibuLock Nail Incisions

Traditional ORIF Incision



FibuLock Fibular Nail

Negotiate

Interview

Demonstrate

Validate



Your nail costs too much compared to my normal plate and screws.

It is imperative to differentiate the FibuLock nail from standard ORIF with plates and screws. The FibuLock nail offers the patient, surgeon, and facility many benefits that plates and screws cannot. See the Bradley Cost-Effectiveness Study.

We have a trauma contract with Synthes.

Seek to learn more about their contract. The FibuLock fibular nail is highly differentiated to the point that it can be approved in most contracted accounts. Simply put, Synthes does not have a length-stable, minimally invasive intermedullary implant for ORIF of ankle fractures. The benefits that the FibuLock nail offers cannot be compared to Synthes' current product offering for ankle ORIF.

What if I need to remove it?

The FibuLock nail is designed to avoid normal hardware irritation/complication issues, but in the event that the nail does need to be removed, it is easily done. There is a dedicated removal kit (AR-8973RK). Please see removal instructions above.



Interview

Demonstrate

Validate

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

- Can I have our system available for your next ankle fracture case?
- We have a great local lab. Would you like to put each of these plates on to see how they fit?
- Can I contact your scheduler to let them know you would like to use us on your next ankle fracture?
- Would you mind if I include you on my initial correspondence to the hospital to get this system approved for you?
- We have a great foot and ankle trauma course coming up, would you be interested in going?
- Would you like to use the FibuLock fibular nail on your next pilon ex fix with fibula fracture?

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Approach

Appendix

Sales Tools

Surgical Technique Guides Ankle Fracture Management System Technique Guide LT1-00109-EN

Syndesmosis TightRope XP Implant System Technique Guide LT1-00082-EN

Brochure Fracture Management Brochure LB1-0020-EN

Videos

Ankle Fracture ORIF – Utilizing the Syndesmosis TightRope Fixation Case Presentation Surgical Technique - VID1-00606-EN

DEX Education Series – Ankle Fracture Plating System Video Series - VID1-00876-EN

FibuLock Nail With the TightRope Fixation System Technique Video Surgical Technique - VID1-01244-en-US Animations

FibuLock Fibular Nail Technique Animation Surgical Technique - AN1-00284-EN

Playsheet FibuLock Sales Trainer (DS-252) DE1-000032-en-US

Competitive Products FibuLock Nail Competitive Matrix CI1-00004-EN

Appendix Ordering Information

Ankle Fracture Set Screw Caddy* (AR-8943C-SC) (included in the AR-8943S)

Product Description	Item Number
Low Profile Screws, Stainless Steel	
2.7 mm Locking	AR- 8827L-10 – 26
Lengths: 10 mm-26 mm (2 mm increments)	
3.0 mm Cancellous Lengths: 10 mm-30 mm (2 mm increments)	AR- 8830-10 – 30
3.5 mm Cortical Lengths: 10 mm-30 mm (2 mm increments), 35 mm-60 mm (5 mm increments)	AR- 8835-10 – 60
3.5 mm Locking	AR- 8835L-10 – 20
Lengths: 10 mm-20 mm (2 mm increments)	
4.0 mm Cancellous, fully threaded	AR- 8840-10 – 24
Lengths: 10 mm-24 mm (2 mm increments)	
4.0 mm Cannulated, short thread	AR- 8840C-30 – 60
Lengths: 30 mm-60 mm (5 mm increments)	

Ankle Fracture/Distal Tibia Screw System (AR-8943C-31) Optional Auxiliary Tray

Product Description	Item Number
Low Profile Screws, Stainless Steel	
2.7 mm Cortical	AR- 8827-10 – 60
Lengths: 10 mm-60 mm (2 mm increments)	
2.7 mm Locking	AR- 8827L-10 – 60
Lengths: 10 mm-60 mm (2 mm increments)	
3.0 mm Cancellous	AR- 8830-10 – 30
Lengths: 10 mm-30 mm (2 mm increments)	
3.5 mm Cortical	AR- 8835-10 – 80
Lengths: 10 mm-60 mm (2 mm increments),	
65 mm-80 mm (5 mm increments)	
3.5 mm Locking	AR- 8835L-10 – 50
Lengths: 10 mm-40 mm (2 mm increments), 45 mm, 50 mm	
4.0 mm Cancellous, fully threaded	AR- 8840-10 – 60
Lengths: 10 mm-50 mm (2 mm increments), 55 mm, 60 mm	
4.0 Cannulated, short thread	AR- 8840C-30 – 60
Lengths: 30 mm-50 mm (2 mm increments), 55 mm, 60 mm	
4.0 mm Cannulated, long thread	AR- 8840CL-30 – 60
Lengths: 30 mm-50 mm (2 mm increments), 55 mm, 60 mm	
Other Implants and Instruments	
BB-Tak, smooth	AR- 13226
BB-Tak, threaded	AR- 13226T
Drill Sleeve for 2.7 mm Locking Screws	AR- 8943-32
Drill Sleeve for 3.5 mm Locking Screws	AR- 8963-06

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