

Small Joint Connection



JANUARY 2008

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Featured Products



NEWS AND NOTES

On behalf of the Small Joint Team, we would first like to wish you all a happy new year. Considering 2007 has been a great year for Arthrex and another successful year for our growing small joint business, I would also like to personally thank all the surgeon customers, instructors and their support teams for helping make 2007 a great year. We all appreciate the dedication and support and look forward to building new relationships and continuing those that have been built in the past year.

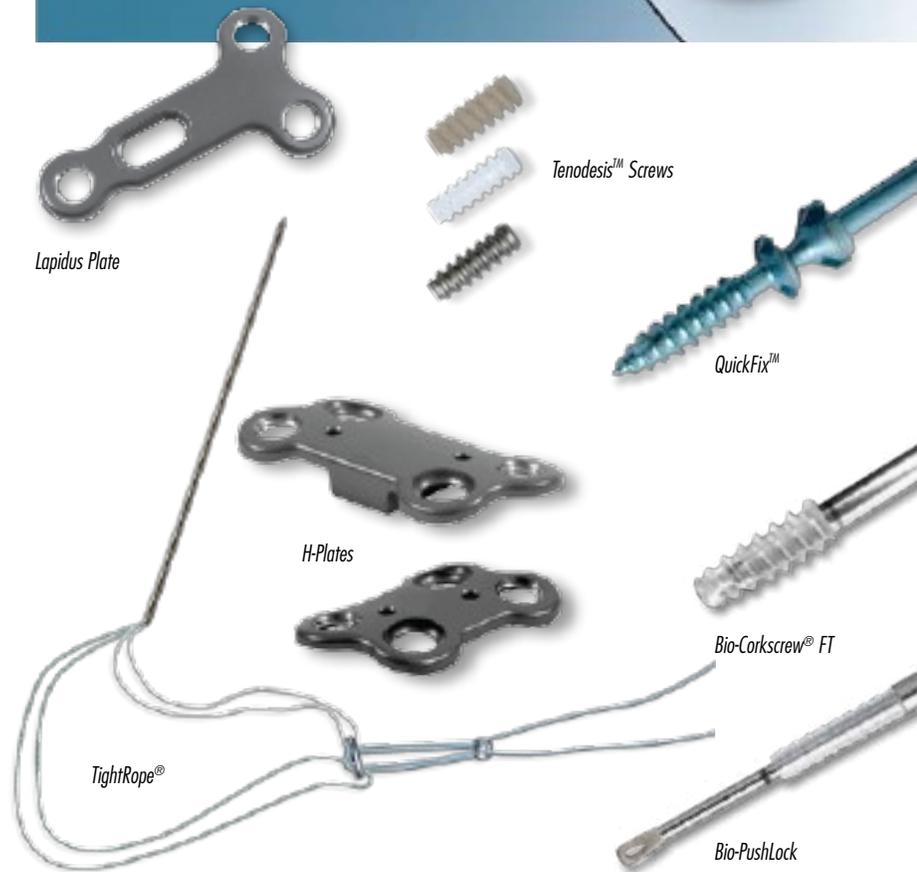
2008 will offer a number of welcome additions. Felix Riano, MD, has joined our team as the Medical Education Specialist. Felix will be responsible for coordinating the medical education activities on a national scale and is already working on developing a new Foot & Ankle Arthroscopy Course for all foot & ankle surgeons. For more information, a complete list of small joint courses for foot/ankle and hand/wrist are available for immediate registration on our website at www.arthrex.com. If there is an area of education that we are not addressing or you have general comments, please contact Felix Riano at felix.riano@arthrex.com. You can also reach Felix at 800-933-7001 x 1306.

2008 also promises to be a busy year for new product additions with many of them in the metal screw and plate category. Some of these are featured here in this newsletter. We are also excited about some very positive feedback from customers with respect to clinical use of the Ankle Syndesmosis and Mini TightRope Systems, as well as the Achilles SutureBridge technique. Please review this newsletter for more information.

As always, we are very serious about the feedback our customers provide and hope that you contact us concerning product performance, medical education and video techniques, as well as the new product concept that comes to mind. We look forward to hearing from you.

Sincerely,
Pete Denove

Group Product Manager, 800-933-7001 x 1171



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U.S. PATENT NOS. 5,964,783; 6,544,281; 6,716,234 and PATENTS PENDING

TIPS AND SURGICAL PEARLS

Mini TightRope



OSTEOTOMY SPARING CORRECTION OF HALLUX VALGUS AND METATARSUS PRIMUS VARUS - THE MINI TIGHTROPE SYSTEM

In January 2007, Arthrex released the Mini TightRope kit as an “osteotomy sparing” surgical implant for the correction of Hallux Valgus, Hallux Varus, Lisfranc’s Ligament, among other pathologies. The results to date have been positive. Many clinicians are now questioning the “gold standard osteotomy” as the best way to go for all patients.

Here are some of the advantages that we have seen early on with this method.

- No osteotomy required to correct IMA
- No shortening of 1st metatarsal
- Potential for earlier rehab and return to normal footwear
- Stabilizes 1st met/cuneiform joint, allowing some degree of mobility
- No disruption of blood supply at the distal 1st metatarsal head
- Patient satisfaction

If hallux valgus and metatarsus primus varus deformities are the result of supporting soft tissue failures rather than bony deformities, then the unstable foundation at the base of the 1st metatarsal may be corrected with a syndesmosis type procedure.

A recent clinical paper in *Foot & Ankle International*, (Syndesmosis Procedure: A Non-Osteotomy Approach to Metatarsus Primus Varus Correction, Daniel Yiang Wu, MD, Hong Kong) offers similar results to the 2+ years of TightRope use for hallux valgus. In his study, Dr. Wu reported using PDS in a cerclage fashion, wrapping the suture around the 2nd metatarsal and through dorsal to plantar drill holes in the 1st metatarsal. Reporting on 11 feet (six patients) on an average of 6 years and 10 months post-op, intermetatarsal and hallux valgus angle corrections were maintained, along with a high degree of patient satisfaction. This suggests some form of fibrous bond between the 1st and 2nd metatarsals.

Early results with the Mini TightRope are promising, with several key elements leading to success. The deformity must be flexible enough to reduce without excessive force. The K-wire should be drilled through the 2nd metatarsal, only once. Drive the K-wire from lateral to medial, exposing the 2nd metatarsal and properly visualizing the dorsal and plantar cortices with a rake retractor and freer elevator respectively. Others have suggested using two Mini TightRopes (one distal and one more proximal) thereby spreading the forces along a greater length of bone.

Our product development team is working hard on further product development and is open to ideas from surgeons currently using the device for these pathologies.

Please contact us with your comments and questions. We look forward to hearing from you.



Lisfranc Repair



Hallux Varus



Distal Hallux Valgus Correction



What's in My Bag?



Chris Coetzee, M.D.



Pierce Scranton, M.D.

FEATURING: CHRIS COETZEE, M.D.; PIERCE SCRANTON, M.D.

Arthrex's recently launched locking Lapidus Plate was designed by two of the leading foot and ankle surgeons in the US, Pierce Scranton, MD, and J. Chris Coetzee, M.D.. After a recent testing of the plate, we were able to catch up with these two surgeons and ask a few questions.

Dr. Scranton's answers are marked in green and Dr. Coetzee's are in blue.

- Q:** What indications do you see as possibilities for the new Arthrex Lapidus Plate?
- A1:** Lapidus procedure, fixation for proximal osteotomy bunion repair, fixation for corrective osteotomy after malunion of a lapidus of proximal osteotomy (I did a big dorsal open wedge osteotomy on Thursday), Lisfranc fixation or fusion. Even calcaneo-cuboid fusion.
- A2:** Mine are the same as Dr. Coetzee's - the plate is indicated for: lapidus bunion procedures, proximal metatarsal osteotomies, and 1st ray lisfranc arthrodesis.
- Q:** What have you used for fixation in the past for these indications?
- A1:** Two or three crossed screws. Occasionally a semi-tubular plate.
- A2:** In the past, 4 mm or 6.5 mm screws were all that worked here. The "H-Plates" were too bulky.
- Q:** What does the plate offer that your previous fixation did not?
- A1:** The Lapidus Plate offers locking fixation, a preloaded 10° correction which adds to the compressive force, and the cross threaded screw for even greater compression.
- A2:** Locking fixation, strength, low profile and possibly earlier WB.
- Q:** Would there be situations where you would use your old method of fixation?
- A1:** Maybe if I have a very skinny patient, or if there was previous soft tissue compromise.
- Q:** What do you think is the most important technique tip for this plate that you would like to pass on to your colleagues?
- A1:** The most important technique tip is to lay the plate on the corrected osteotomy and fix it with the BB-Taks. This guarantees perfect alignment so that the compression and fixation is optimal.
- A2:** I agree with Dr. Scranton, locking screws don't pull the plate down to the bone, so make sure the contact is perfect by pinning it down with the BB-Taks. Also, you must use the guide to drill the locking screws.
- Q:** Will this plate change your post-op protocol, and if so, how?
- A1:** The plate may allow my patients to weight-bear earlier since the fixation is more secure.
- A2:** I think for now it will stay the same, until I know they do well. My protocol is a post-op bunion shoe, PWB (50%) with weight on their heel right away. They can increase WB at 6-8 weeks if the fusion looks OK.
- Q:** Anything else that you would like to add?
- A1:** Glad to see the results of the testing! The Arthrex plate proved to be 38% stronger than crossed 4 mm screws. It is going to rock!

Midfoot Fixation Plates



THE LAPIDUS PLATE

Designed to provide excellent fixation for a lapidus procedure, the Lapidus Plate offers the foot and ankle surgeon an anatomically contoured and configured option for procedures in the midfoot. This addition to the Low Profile Plating System allows the surgeon the choice of placing a Lag Screw across the TMT joint, or placing locking or nonlocking screws in the other plate holes.



Locking Option - The two proximal and most distal holes allow the surgeon to choose a fixed-angle locking or variable-angle nonlocking option, depending on the needs of the patient

Compression Option - The inner slot can accommodate an interfragmentary screw or generate compression when drilled eccentrically in arthrodesis applications

Minimized Profile - Low profile plates and screw heads reduce soft tissue irritation and the need for removal

Anatomic Contour - Optimizes construct strength, simplifies surgical technique and reduces soft tissue irritation

Anodized Finish - Dramatically improves smoothness

Screw Options - 3.5 mm cortical locking and 4 mm cancellous

Lapidus Plate

AR-8941

MIDFOOT FEEDBACK

Zac Price, Ramsay Medical

"I had two great cases today I thought you might like to know about:

The first case was a revision of a failed fusion of the 3rd, 4th & 5th mets where staples had been used previously. The staples practically fell out on removal. He used the small H-Plate to fuse the 3rd & 4th met/cuneiform joint and the 5th met/cuboid joint. He was very happy. He and the staff thought the tray was simple to use and put together very well. He felt that he had great compression and really liked how low profile the plate actually is.

He liked it so well, he decided to use the Lapidus Plate for his following case, which he labeled a Lisfranc fracture and dislocation. He said the plate size was perfect and that he rarely chooses to do lapidus bunions but given how easy the plate is to use and the fixation he feels he is getting, he is going to seriously consider using this plate routinely when he has a patient where a lapidus bunion is indicated."



H-PLATES

Designed to provide excellent fixation for fusions and osteotomies, these plates offer the foot and ankle surgeon a comprehensive option for procedures in the midfoot. These additions to the Low Profile Plating System come with and without wedge blocks, and in a variety of lengths to fixate lateral column lengthenings, calcaneocuboid arthrodesis, talonavicular arthrodesis and other less common procedures.

Left or Right Slants - Fits a variety of indications

Wedge Option - Wedges save OR time and eliminate the need to harvest a tricortical wedge from the iliac crest

Locking Option - The outermost holes allow the surgeon to choose a fixed-angle locking or variable-angle nonlocking option, depending on the needs of the patient

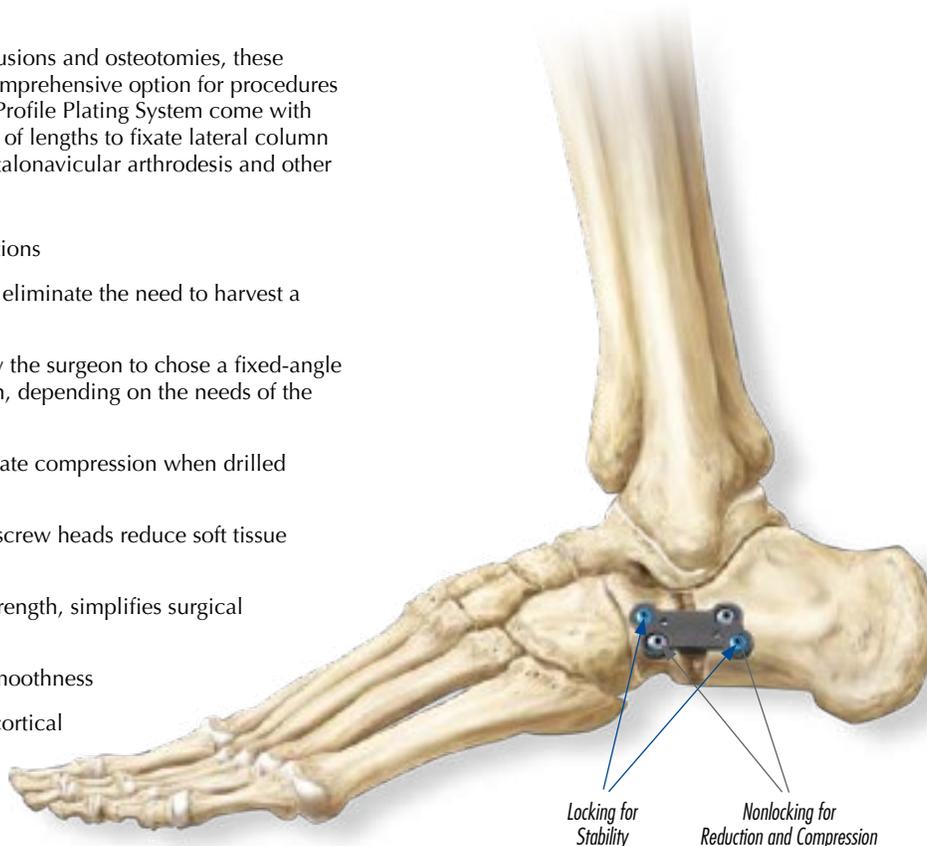
Compression Option - The inner slots generate compression when drilled eccentrically in arthrodesis applications

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Anatomic Contour - Optimizes construct strength, simplifies surgical technique and reduces soft tissue irritation

Anodized Finish - Dramatically improves smoothness

Screw Options - 3.5 mm cortical, 3.5 mm cortical locking and 4 mm cancellous



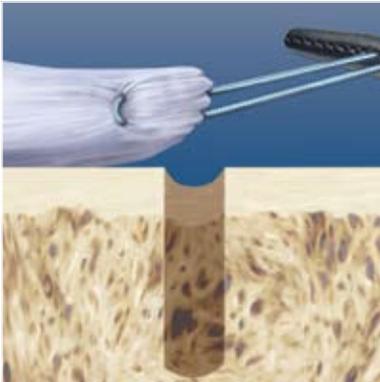
MIDFOOT PLATING MODULE FOR H-PLATES AND LAPIDUS PLATE

This module of the Low Profile Plating System houses the Lapidus and H-Plates along with the 3.5 mm cortical, 3.5 mm cortical locking and 4 mm cancellous screws. The instrumentation for these implants is straightforward and easy to use, assisting the surgeon with distraction, provisional fixation and other elements of the procedure. This module is stackable with the forefoot osteotomy, forefoot fusion and other future modules.

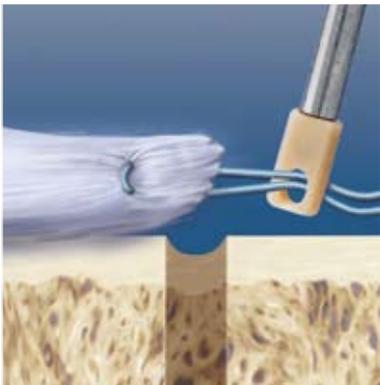




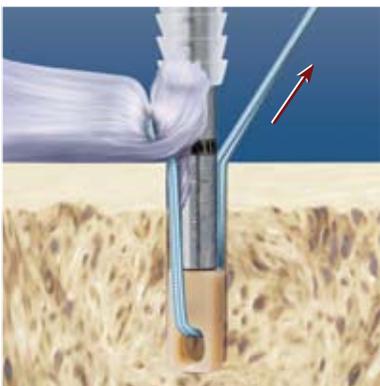
2.5 mm PushLock®



Place a size 0 or 2-0 FiberWire® stitch into the tendon or ligament and drill or punch a hole at the desired attachment location.



Pass the suture ends through the eyelet.

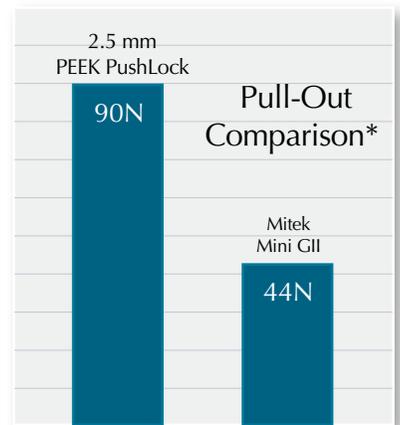


Push the eyelet tip to the bottom of the hole, allowing suture tails to follow. Adjust tension one suture at a time until optimal tension is achieved.

OPTIMIZE TENSIONING AND FIXATION WITHOUT KNOT TYING WITH THE NEW 2.5 MM PUSHLOCK

The 2.5 mm PushLock Suture Anchor provides a secure means of knotless fixation in the hand and wrist, as well as in foot and ankle applications. Accommodating two strands of either size 0 or 2-0 FiberWire, this two-piece anchor enables a no profile repair that is quick and straightforward.

The 2.5 mm PushLock uses a PEEK eyelet to place the sutures at the bottom of a drill hole, allowing the surgeon to precisely tension and lock the sutures in place by impacting the tak portion of the anchor. Both the high strength radiolucent PEEK and the absorbable PLLA 2.5 mm PushLock optimize tissue tension and fixation without knot tying.



*data on file

PushLock Implants:

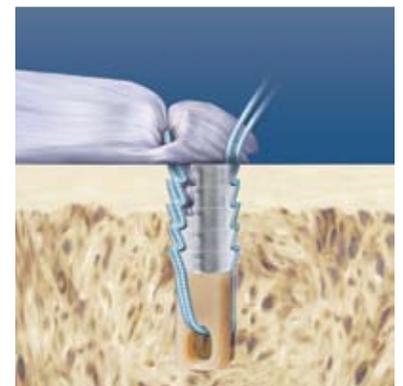
Bio-PushLock, 2.5 mm x 8 mm	AR-8825B
PEEK PushLock, 2.5 mm x 8 mm	AR-8825P

PushLock Instrumentation:

Mini Bio-SutureTak Disposables Kit (disposable punch for soft bone, 1.8 mm & 2 mm drills for harder bone, drill guide)	AR-1322DS
2-0 FiberWire, 18 inches w/Tapered Needle, 17.9 mm 3/8 circle	AR-7220
0 FiberWire, 38 inches w/Tapered Needle, 22.2 mm 1/2 circle	AR-7250



Impact metal striking head on the back of the PushLock driver to impact the tak portion of the anchor into the hole and lock the sutures.



Rotate the handle six full turns counter-clockwise to unthread from the eyelet. Remove the handle. Cut the sutures flush.

QuickFix

QUICKFIX SCREW

The “snap off” QuickFix Screws are self-drilling, self-tapping screws used primarily for metatarsal osteotomies (Weil, Chevron) as well as fixation of bony fragments of the foot, ankle, hand, and wrist. The color-coded 2 mm screws come in 1 mm increments whereas the 3 mm screws come in 2 mm increments. The QuickFix Screws are made of titanium alloy, are compatible with most K-wire and pin drivers, and offer the surgeon quick and easy fixation for a number of small bone procedures. The 3 mm QuickFix Screws can also be used for the nonlocking holes of the Low Profile MTP Plate™.

2 mm Screws:

QuickFix Screw, clear, 2 mm x 10 mm	AR-8930-10
QuickFix Screw, magenta, 2 mm x 11 mm	AR-8930-11
QuickFix Screw, blue, 2 mm x 12 mm	AR-8930-12
QuickFix Screw, purple, 2 mm x 13 mm	AR-8930-13
QuickFix Screw, green, 2 mm x 14 mm	AR-8930-14

3 mm Screws:

QuickFix Screw, yellow, 3 mm x 13 mm	AR-8931-13
QuickFix Screw, light blue, 3 mm x 15 mm	AR-8931-15
QuickFix Screw, aqua, 3 mm x 17 mm	AR-8931-17
QuickFix Screw, bronze, 3 mm x 19 mm	AR-8931-19

QuickFix Screw System (AR-8930S) includes:

End Cutter, QuickFix Screw	AR-8930R
Drive Shaft for 2 mm QuickFix Screw	AR-8930D
Drive Shaft for 3 mm QuickFix Screw	AR-8931D
Depth Guide for 3 mm QuickFix Screw	AR-8930G
Forceps	AR-8930F
1.3 mm Drill Bit for 2 mm screw	AR-8930D-13
Drill Bit, 2 mm	AR-4160-20
Low Profile Screw and Plate System Instrumentation Case	AR-8930C



CONSIDER THESE SURGICAL PROCEDURES:

- Weil Osteotomy Fixation
- Chevron Osteotomy Fixation
- MTP Fusion



1 With an oscillating saw, make the bone cut in a horizontal fashion, parallel to the sole of the foot. While the bone cut is generally 2-3 mm, cuts may be varied in a patient with pes planus or pes cavus deformities.



2 Following the osteotomy, the metatarsal head will shift proximally.

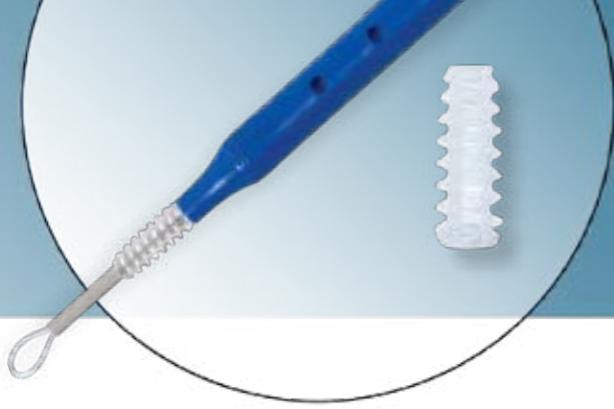


3 After selecting the appropriate size screw, advance the self drilling/tapping screw with a 2 mm wire driver.



4 The repair is complete when the head is flush and snap off occurs. There is a driver in the set in the event that the screw snaps off too early. If the screw does not break off, gently exert pressure to one side of the screw as to not affect the fixation of the construct.

Disposable Bio-Tenodesis System



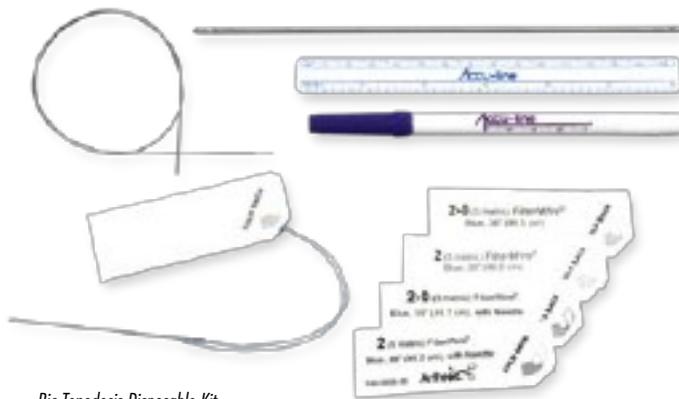
NEW BIO-TENODESIS DISPOSABLES

The Bio-Tenodesis Screw product line now includes a disposable driver/screw option. Used in conjunction with the series of disposable drills and the disposables kits, the preloaded disposable driver comes with a 5.5 mm x 15 mm screw and #2 FiberWire suture positioned in loop form at the tip of the driver. The blue driver is also compatible with the 4.75 mm and 6.25 mm size screws sold separately.

<u>Disposable Tenodesis Driver w/5.5 mm Screw and #2 FiberWire</u>	AR-1555DS
includes: driver, 5.5 mm screw, preloaded #2 FiberWire loop	
<u>Bio-Tenodesis Disposables Kit</u>	AR-1676DS
includes: Short Guide Pin, Suture Passing Wire, Skin Marking Pen, ruler, #2 FiberLoop w/Straight Needle, two #2 FiberWire, two 2-0 FiberWire	
<u>Small Diameter Bio-Tenodesis Disposables Kit</u>	AR-1677DS
includes: Short Guide Pin, Suture Passing Wire, Skin Marking Pen, ruler, 0 FiberWire, 0 TigerWire, 2-0 FiberWire, 2-0 FiberLoop	

<u>Cannulated Drill Bits (accepts 2.4 mm K-wires) 2.5 mm cannulation, for use with AR-1676DS:</u>	
Cannulated Drill Bit, 5 mm	AR-1676C-50
Cannulated Drill Bit, 5.5 mm	AR-1676C-55
Cannulated Drill Bit, 6 mm	AR-1676C-60
Cannulated Drill Bit, 6.5 mm	AR-1676C-65

<u>Cannulated Drill Bits (accepts 1.57 mm K-wires) 1.7 mm cannulation, for use with AR-1677DS:</u>	
Cannulated Drill Bit, 4 mm	AR-1677C-40
Cannulated Drill Bit, 4.5 mm	AR-1677C-45
Cannulated Drill Bit, 5 mm	AR-1677C-50
Cannulated Drill Bit, 5.5 mm	AR-1677C-55



Bio-Tenodesis Disposable Kit



Disposable Drill



Disposable Tenodesis Driver

TIGHTROPE® Syndesmosis Repair Kit

Four-stranded loop of #5 FiberWire® between two titanium or stainless steel buttons

TightRope Advantages

- Fatigue life over two times that of standard metal screw
- Full weight-bearing up to three weeks earlier than metal screws*
- Allows some normal motion of the fibula during gait cycle

Clinically Proven Effective

"I was a bit skeptical when I started using the TightRope. I was not sure if it would stand up to the forces around the ankle with use after fixation. From a clinical perspective it has been excellent so far. There were no early or late failures."

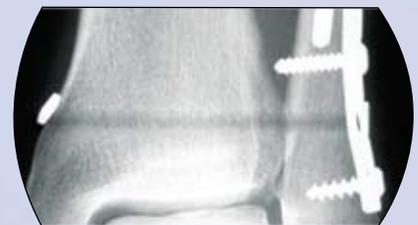
J. Chris Coetzee, M.D., Orthopedic Foot and Ankle Specialist, Minneapolis, MN
Clinical study presented at AOFAS July 2007

"The micromotion allowed is necessary for a healthy syndesmotom joint. The stability provided is more than adequate to allow for appropriate healing of the syndesmosis."

Todd Oliver, M.D., Director of Orthopedic Trauma
Boone Hospital Center, Columbia, MO

"The TightRope is as effective as a syndesmotom screw, with a significantly quicker return to full weight-bearing without the need for a second surgery for device removal. The TightRope group also maintained tibial/fibular overlap better than the screw group."

Mark Hardy, D.P.M., Director Foot & Ankle Trauma Ohio Region
Kaiser Permanente, Cleveland, OH
Clinical Study presented at ACFAS March 2007



ANKLE SYNDESMOSIS REPAIR



Lisfranc Repair



Distal Hallux Valgus Correction



Hallux Varus

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*Clinical data on file

Scientific Update

TREATMENT OF SYNDESMOSIS DISRUPTIONS: CONVENTIONAL SCREW FIXATION VS. TIGHTROPE FIBERWIRE FIXATION

*A Prospective, Randomized Study, J. Chris Coetzee, MD
Associate Professor, University of Minnesota
Minnesota Sports Medicine & Twin Cities Orthopedics*

Open reduction and screw fixation is currently the accepted treatment for displaced syndesmoses injuries. Despite reduction and stable internal fixation, these injuries do not have uniform excellent outcomes. There are specific reasons for it. The ankle mortise in a “closed packed” joint and any disruption of the mortise can lead to significant dysfunction of the mechanics of the joint. Lloyd et al published in the Foot Ankle International in November 2006 their confirmation of previous studies that showed that as little as 1 mm of lateral shift in the ankle mortise due to a syndesmosis injury resulted in a 40% loss of contact surface area in the ankle.

Gardner, Helfet et al published in the Foot Ankle International October 2006 that even in a level 1 trauma center there was a 52% malreduction of the tibiofibular syndesmosis in ankle fractures with screw fixation.

The syndesmotic functions are to maintain talar reduction, transfer load to fibula and allow for fibular motion. During stance, there is 2.4 mm distal motion of the fibula, while from plantarflexion to dorsiflexion there is 1 mm of widening and 2 deg of external rotation. Most, if not all, of this motion is gone with screw fixation of the syndesmosis, with potential loss of function in the syndesmosis and ankle.

The objective of this study is to compare screw fixation to the fiber wire fixation.

All syndesmoses injuries, with or without ankle fractures are followed and at this point the average time is 18.5 months (12 months to 28 months). These patients were enrolled in a prospective, randomized clinical trial comparing traditional screw fixation to TightRope (Arthrex) FiberWire. Any associated ankle fractures were treated in a conventional manner.

Evaluation was performed with clinical examination, radiography, AOFAS ankle and hindfoot Scale, visual analog scale and a functional questionnaire.

At this point there are eight patients in each group with at least one year follow-up. The potential advantage of the FiberWire fixation is that it still allows some of the normal rotation and proximal distal motion of the fibula during the normal gait cycle.

The follow-up is short, but at a minimum follow-up of one year the AOFAS ankle and hindfoot score for the TightRope group was 94 (82 -100) and the Screw fixation group was 88 (80-100). The patients in the TightRope group had better range of motion than the screw fixation, and also subjectively less stiffness and discomfort.

ROM WITH TIGHTROPE

	Normal	Syndesmosis
6 month N-8	DF 12 (6-25) PF 57 (43-85)	DF 7 (0-20) PF 44 (29-80)
18 month N-5	DF 12 (6-226) PF 58 (44-84)	DF 11 (4-20) PF 53 (37-80)

ROM WITH SCREWS

	Normal	Syndesmosis
6 month N-8	DF 12 (2-25) PF 55 (40-82)	DF 5 (0-12) PF 39 (23-76)
18 month N-5	DF 10 (2-25) PF 55 (42-80)	DF 8 (2-20) PF 43 (28-70)

Complications included one broken screw in the screw group and one patient that developed an infection in a FiberWire fixation that required removal of the wire after six months. At this early stage FiberWire fixation appears to be at least equal in result as conventional screw fixation. The potential advantage is that it still allows for the normal motion in the syndesmosis complex, which appears to benefit the patient.



AP and lateral of a severe fracture dislocation of an ankle with obvious disruption of the syndesmosis.



15 months after an open reduction and fixation of the fracture. TightRopes were used through the bottom holes of the plate. Excellent restoration of the ankle mortise.



Conventional screw fixation. Due to the high fibula fracture the fracture was not fixed, but a short plate and two screws were used for the syndesmosis to prevent superior migration of the fibula.



Small Joint Education

FOOT AND ANKLE COURSES

Designed for foot and ankle specialists these courses introduce the latest surgical techniques for reconstruction of the foot and ankle using minimally invasive strategies.

Location	Date	Location	Date
Los Angeles, California	August 23, 2008	Naples, Florida	March 17, 2008
	November 8, 2008		March 24, 2008
Tracy, California	January 18, 2008		April 11, 2008 (Arthroscopy)
	January 19, 2008		June 14, 2008
	May 2, 2008		July 14, 2008
	May 3, 2008	December 13, 2008	
	October 17, 2008	Scottsdale, Arizona	April 5, 2008
			August 29, 2008

Please contact your local Arthrex representative for more information and to request a lab reservation.

For more information contact your Arthrex sales representative.
Need to find your sales representative? Call Arthrex Customer Service at 1-800-934-4404.

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Felix Riano	Clinical Specialist	1306

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