

InternalBraceTM

Ligament Augmentation Repair

Faculty Forum Virtual Roundtable

Moderator



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Participating Panelists



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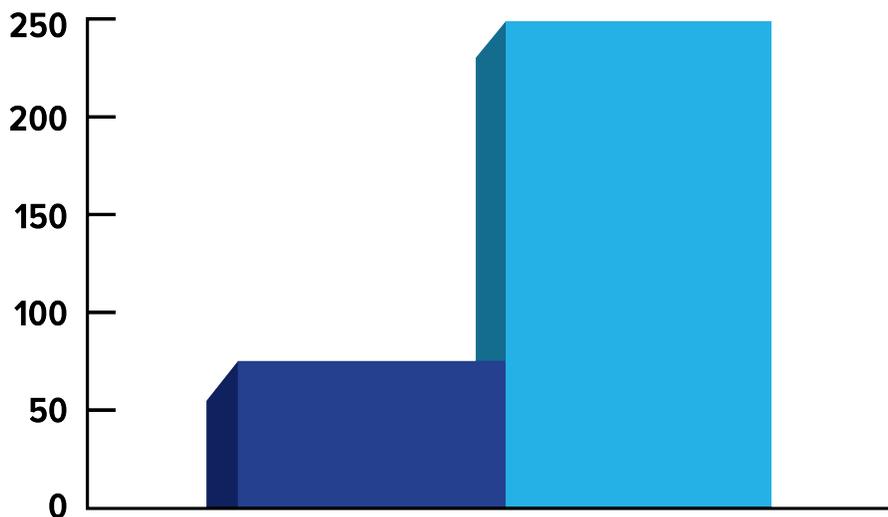
The *InternalBrace* surgical technique is intended only to augment the primary repair/reconstruction by expanding the area of tissue approximation during the healing period and is not intended as a replacement for the native ligament. The *InternalBrace* technique is for use during soft tissue-to-bone fixation procedures and is not cleared for bone-to-bone fixation.

Add Strength and Protection to Your Brostrom Repairs



In an effort to address the concerns and limitations of traditional Brostrom repairs, Arthrex[®] organized a faculty forum virtual roundtable with thought leaders discussing their experiences with *InternalBrace*[™] ligament augmentation repair for lateral ankle instability.

Ultimate Failure (Newtons) at Time Zero



■ ATFL repaired with Brostrom alone [Am J Sports Med. 2012;40(11):2590-2596]

■ ATFL repaired with Brostrom and *InternalBrace* procedure [Am J Sports Med. 2014;42(2):405-411]

Q Why have Brostroms been considered the gold standard when some of the literature indicates that patients have to step down in their activities? Shouldn't this be considered a failure or complication?

Dr. Cicchinelli

An often overlooked and underemphasized functional outcome measure is the return to desired activity level. The AJSM article speaks to that. It isn't necessarily enough that patients get back to some activity; they would like to resume what they previously enjoyed. So this is, in a sense, a failure of an ideal and full recovery, not a complication.

Dr. Fleming

I think the paper by Mafulli demonstrates the significance of ankle instability in quality of life regarding inability to return to activity, concerns about future injuries and the association between ankle instability and ankle arthritis. I think this is a failure of their technique. I would say that their results are in line with what I experienced in my patients prior to the implementation of the *InternalBrace*™ ligament augmentation.



Please scan QR code for SwiveLock® anchor video showing blood and bone marrow flow through the anchor.

Q Why do you feel it is important to utilize *InternalBrace* ligament augmentation to augment your Brostrom procedure?

Dr. Fleming

Clearly, the biggest advantage is the strength that it provides. The increase in mechanical strength of the repair increases the durability, and decreases the failure rate. The *InternalBrace* ligament augmentation not only strengthens the initial repair but protects the soft tissues until they reach the necessary maturity.

Dr. Hardy

It provides me the assurance of knowing my primary Brostrom repair is protected; thus, allowing the ability to return these patients to pre-injury form.

Dr. Shibuya

Many patients have hyper flexible soft tissue that can result in stretching of the repaired ligament and loss of correction. Many don't recognize this because many patients can become less active after surgery. But, if you want to keep your patients active, this phenomenon is important to recognize.

Q What are your concerns with current Brostrom repairs?

Dr. Hardy

Attenuation of the repair. There may be biomechanical and connective tissue contributions to the instability which causes me to protect these patients longer post Brostrom; however, use of the *InternalBrace* ligament augmentation limits if not alleviates those concerns.

Dr. Shibuya

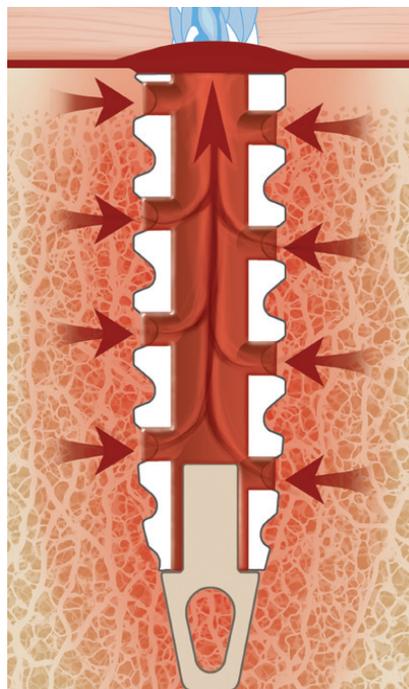
Some patients are too flexible or do not possess good soft tissue to be repaired; therefore, we have to assume or rely on good soft tissue integrity.

Dr. Todd

I have two concerns with the current Brostrom repair. My first concern is with patients with ligamentous laxity disorders. Most of these patients have very poor tissue, which makes the repair weak and destined to fail. Second, with the athletes that I treat, the standard Brostrom requires an extended period of immobilization/non-weightbearing. With long periods of non-weightbearing this requires a significant amount of time away from their sport. Tissue quality in one's repair is the single most important factor. If the tissue is poor the repair is bound to fail.

“The *InternalBrace* ligament augmentation not only strengthens the initial repair but protects the soft tissues until they reach the necessary maturity.”

-Dr. Fleming



SwiveLock anchor cannulation and vents allow blood and bone marrow to flow through the anchor.

Q | What compelled you to use the *InternalBrace*™ construct to augment your Brostroms?

Dr. Fleming

I never had a great sense of security on the table with the Brostrom. The tissue quality is generally subpar and achieving secure fixation has always been challenging. I feel that the Brostrom repair loosens over time, which is problematic for everyone, but especially for the young athlete. And lastly, I wanted to find a substitute for the allograft reconstructions that we were doing. I struggle with achieving equal tension on both limbs of the repair and occasionally they will stretch out for various reasons. A modified *InternalBrace* ligament augmentation has drastically reduced the number of allograft stabilizations that we perform.

Dr. Hardy

I first started using it in spring ligament repairs/augmentation and quickly saw its utility in framing around other soft tissue repairs.

Dr. Todd

When examining their surgical failures/recurrences a surgeon will always look for alternatives. Poor tissue quality led to recurrence and multiple procedures that required large surgical exposure and extended immobilization. I used an *InternalBrace* ligament augmentation on an Ehlers Danlos patient with severe laxity; this patient was able to ambulate two weeks following surgery and has had no recurrence in over one year.

Q | We often hear “I never met a Brostrom that needed augmentation” or “My Brostroms all do fine”. Knowing the clinical value, what would be your response to those conversations?

Dr. Cicchinelli

In our health care climate once folks are healed and basically doing ok they disappear. It isn't user friendly to call them all back in for a long-term follow-up such as 1-3 years or 7-10 years. As the ASJM article reports, not all patients are back to doing what they would like based on the Brostrom alone.

Dr. Fleming

The patient is still exhibiting mechanical instability but their symptoms have resolved. Long term stability is crucial to the health and maintenance of the ankle joint, and I believe the traditional Brostrom cannot consistently provide this.



Dr. Hardy

Never say never or always. We should constantly be evaluating our results and listening to our patients. In some patients, where marked hypermobility exists, a traditional Brostrom will be inadequate.

Dr. Shibuya

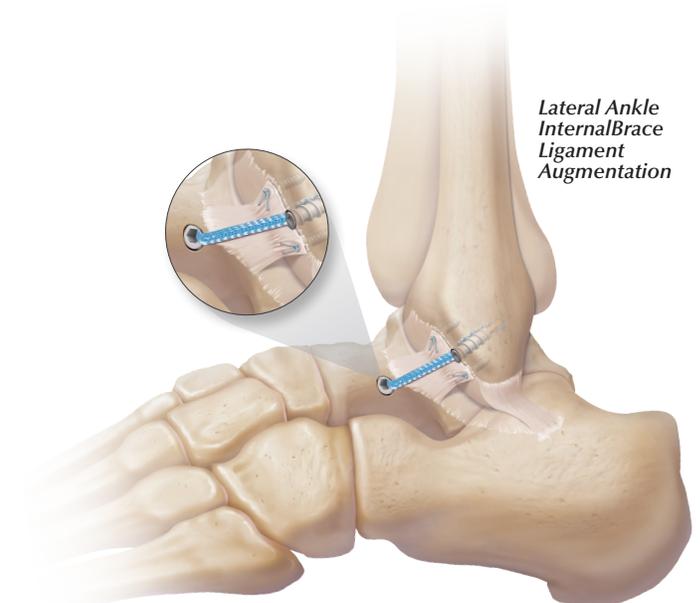
“All do fine” is a relative term. Every time surgeons get into this type of discussion, regardless of a surgical procedure, each surgeon is often talking about a different thing. To some surgeons, casting for six weeks is “fine” while others won't call it a success unless the patient gets back to normal activity within six weeks. Some may not feel “fine” unless the procedure lasts for more than five years while some don't even follow up with the patients for more than three months. Some feel that a failure after noncompliance is on patients while others feel that it is part of unfavorable outcomes.

“The Brostrom is a great procedure but the *InternalBrace* ligament augmentation improves outcomes when recurrence is a concern.”

-Dr. Cicchinelli

Dr. Todd

I was one who would often say these exact words. The standard Brostrom can be effective but there are circumstances where it will fail. The ease and reproducibility of the *InternalBrace* ligament augmentation have allowed me to treat patients who would need a larger exposure. The Brostrom is a great procedure but the *InternalBrace* ligament augmentation improves outcomes when recurrence is a concern.



Q It is understood that this procedure is relatively new with limited, long term clinical follow up. Can you comment on the outcomes and your experience with your patients you have treated? Please explain the difference between standard Brostrom repair and those that have *InternalBrace*™ ligament augmentation repair?

Dr. Cicchinelli

The difference is in the security of repair at time 0, leaving the OR, that allows confidence in advancing the rehab which in turn discourages all sorts of post immobilization deleterious effects on the lower extremity muscles, tendons, and all soft tissues. Essentially disuse disease is avoided.

Dr. Shibuya

For high-level athletes, non-compliant patients, heavy patients, those with chronic instability with significant loss of proprioception, the *InternalBrace* ligament augmentation can “protect” the Brostrom while the soft tissue is being healed and reorganized.



Please scan QR code for four months second look *FiberTape*® suture video.

Q What have been the most positive effects of the *InternalBrace* ligament augmentation for your patients?

Dr. Shibuya

It can protect the Brostrom repair if a patient has an incident, such as fall or non-compliance during the postoperative period.

Q Surgeons often speak of clinical studies before trying something new. Why try the *InternalBrace* ligament augmentation now? What are the minimum expectations you have?

Dr. Cicchinelli

The minimum expectation is improvement on the Brostrom Gould which has been considered the gold standard.

Dr. Hardy

As surgeons, we are always looking to evolve and provide our patients with the best technology. The implants and the technology are not new – just the technique and application.

Dr. Shibuya

The *InternalBrace* ligament augmentation technique is simple and reproducible. The benefit simply outweighs the risk.

Dr. Todd

When I look at new technology I look at the science behind it. The *InternalBrace* ligament augmentation makes sense to me, you are not recreating the ligament, you are creating a door stop. You are allowing the tissues to heal with protection. You are not burning any bridges; you are advancing the standard Brostrom.



Please scan QR code for six weeks second look *FiberTape* suture video.

Q What are the technique pearls you have learned and can pass along?

Dr. Cicchinelli

Double check the talar drill hole placement, even with fluoro if necessary, to ensure you aren't angled too high or too low. Then place a K-wire in this hole through the overlying retinaculum for ease of insertion of the talar SwiveLock® anchor.

Dr. Fleming

Placing a hemostat beneath the *InternalBrace* ligament augmentation is a rough estimate of the tension. Often I will leave the implant/anchor body engaged on the SwiveLock driver and test the stability. If it's too loose or too tight it can still be modified and re-tensioned. Lastly, to anchor the talus in the correct position I place a bump beneath the Achilles tendon which allows the talus to seat within the mortise and then the repair is carried out.

Dr. Shibuya

Turning the paddle clockwise to lift the tip of the device after inserting the screw to make sure that the screw is seated all the way in the bone before removing it completely.

Dr. Todd

Make sure to tap the talus and leave the Tap within the talus. I always tension to the fibula. If you tension to the talus visualization is much more difficult. Make sure never to put the *InternalBrace* ligament augmentation repair intraarticular. This is not a ligament, and I believe that if it is used as a ligament/intraarticular you will have impingement. I have had to take out several from others who have used it in an intraarticular fashion.



Please scan QR code for Clanton technique video.

Q In simple terms, explain your surgical technique.

Dr. Cicchinelli

I do a standard Brostrom Gould repair dissection, prepare drill holes in the fibular rim and talar neck, then complete the soft tissue stabilization and add the *InternalBrace*[™] ligament augmentation repair over the retinacular repair. I seat the talar SwiveLock[®] anchor first and then the fibular.

Dr. Hardy

I release the capsule and ligament remnant off of the distal fibula. The exposed portion of the talar dome is inspected. The anterior portion of the distal fibula is then “roughened” up to achieve greater soft tissue attachment. The talar insertion of the ATFL is prepared for the 4.75 SwiveLock anchor. Attention is then directed to the distal fibula where it is divided into thirds. The proximal and distal thirds receive the 3 mm PushLock[®] anchors and the central third is prepared for the 4.75 SwiveLock anchor. The sutures from the 3 mm PushLock anchors are passed through the capsule and extensor retinaculum; they are not tied. A bump is then placed beneath the achilles and the ankle is reduced to neutral. The FiberTape[®] suture and SwiveLock anchor are then tensioned appropriately. The sutures from the PushLock anchor are now tied. If more tension is required, all of the tails including the *InternalBrace* suture may be gathered and placed into a PushLock anchor in the lateral malleolus.

Dr. Todd

I use a lateral incision that is standard for a Brostrom with the incision 1 cm extended distally. I obtain my visualization of all my landmarks (distal fibula, talus). I like to place my primary anchors both at 10 and 20 mm superior to the distal tip of fibula. I favor the DEX 2.9 BioComposite[™] PushLock anchor because it allows me to preload a variety of sutures, such as the recently available SutureTape[™] suture. I keep the foot in neutral/dorsiflexion, then proceed to drill/tap the talus and insert the 4.75 SwiveLock anchor preloaded with FiberTape suture. I complete my standard Brostrom repair as usual. I then drill/tap the fibula in-between the primary anchors and slightly superior. Keeping the foot in neutral I bring the two tails of FiberTape suture to my fibula hole. (Tensioning is always performed with a closed hemostat inferior to the FiberTape suture to prevent overtightening.)

Q Describe the optimal technique for tensioning the final construct.

Dr. Cicchinelli

The ankle is placed at 90°, any bumps are removed from under the heel to prevent any undesired anterior drawer pressure and a hemostat is placed under the *InternalBrace* suture as the fibular SwiveLock anchor is tightened down.

Dr. Hardy

After placing the ankle in the desired position (neutral sagittal plane and comparable amount of inversion to the contralateral ankle) and pinning it, I place a Kelly hemostat under the suture to ensure it is not overtightened.

Dr. Todd

Proper tensioning is of vital importance. I utilize a hemostat to palpate the tension of the suture. I make sure that the ankle is in neutral and not everted.



Please scan QR code for Dr. Gates testimonial and technique video.

Q Describe your post-op rehab protocol? What is your post-op rehab protocol for your lateral ankle repairs without *InternalBrace* ligament augmentation?

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InternalBrace Ligament Augmentation:

Dr. Cicchinelli

A cast for nonweight-bearing for two weeks, then full weight-bearing into a fracture boot with removal for passive range of motion and bathing. Physical therapy begins at one month and into an ankle brace between 4 - 6 weeks.

Dr. Fleming

Range of motion exercise is begun when the wound is sealed. Protected weight-bearing may begin in two weeks if the patient can tolerate it. A home exercise program is prescribed and full return to activity is allowed at 12 weeks.

Dr. Hardy

Two weeks nonweight-bearing in cast; full weightbearing in boot with active range-of-motion; PT at four weeks; light running at six weeks and lateral maneuvers at eight weeks.

Dr. Shibuya

Immediate weight-bearing with a removable boot. In three weeks, the patient is to start range of motion exercise in the sagittal plane only. The patient is then to transition to supportive shoe gear with a lace-up ankle brace for two more additional weeks before transition completely to regular shoe gear.

Dr. Todd

1. Progress to weight-bearing with boot at two weeks. The first two weeks is nonweight-bearing (once the skin is healed patient can begin to put weight on the extremity).
2. Two weeks begin weight-bearing and physical therapy (No Inversion)
3. At five weeks transition to an ankle brace, advance therapy
4. At seven weeks begin running and ballistic movements

For a standard Brostrom without *InternalBrace*™ Ligament Augmentation the rehab is as follows:

Dr. Cicchinelli

A short leg cast for four weeks, nonweight-bearing the first three weeks, then conversion to a fracture walker boot, full weight-bearing, and initiation of physical therapy.

Dr. Fleming

Prior to the application of the *InternalBrace* ligament augmentation, my patients would be nonweight-bearing for six weeks.

Dr. Hardy

Three weeks non-weightbearing in everted cast; followed by boot for six weeks; transition to ankle brace with PT to follow; running and lateral maneuvers around 12 weeks.

Dr. Todd

1. Nonweight-bearing four weeks
2. At four weeks progress to cam boot
3. At eight weeks begin physical therapy progress to an ankle brace
4. No ballistic movements until week 16



Please scan QR code for patient walking six weeks post-op video.

Q | The *InternalBrace* ligament augmentation System comes with 4.75 mm SwiveLock® anchors and 3.5 mm SwiveLock anchors. Where do you use the 3.5 mm & 4.75 mm SL anchors respectively?

Dr. Cicchinelli

The 4.75 mm SwiveLock anchor in the talus and the 3.5 mm SwiveLock anchor in the fibula.

Dr. Fleming

I actually use two 4.75 mm SwiveLock anchors for the repair. Talar purchase is never an issue but the fibula may not provide sufficient strength for the anchor.

Dr. Hardy

I use the larger 4.75 mm anchor in the fibula.

Dr. Shibuya

The 3.5 mm is always in the anterior-distal fibular malleolus. The 4.75 mm anchor(s) go in the talar neck.

Dr. Todd

I use the 3.5 mm SwiveLock anchor in the distal fibula and the 4.75 mm SwiveLock anchor into the talus.



Please scan QR code for patient walking 12 days post-op and six weeks post-op video.

Q | When would you use *InternalBrace* ligament augmentation in your lateral ankle instability cases? Do you incorporate a calcaneofibular ligament (CFL) limb, if so how often (what percent of the time)?

Dr. Cicchinelli

I have not seen the need to repair the CFL on a regular basis.

Dr. Fleming

I use the *InternalBrace* ligament augmentation procedure to recreate the CFL if the stress inversion is grossly positive prior to surgery or there is documented STJ instability.

Dr. Hardy

I use it as an augment to my Brostrom procedures. I do not address the CFL.

Dr. Shibuya

When treating patients with chronic instability, they often lack functional stability and the reflex and proprioception to “fight” inversion are compromised. About 20% of the time the CFL limb is useful which consists of lots of revision work from previously failed Brostrom referred to my clinic.

Dr. Todd

With my patients who have lateral ankle instability I utilize the *InternalBrace*™ ligament augmentation procedure when there is severe instability. I do not incorporate a CL limb as I do not believe this to be necessary.

Q | What are your thoughts on indications of *InternalBrace* ligament augmentation versus when to do a full allograft reconstruction with tenodesis screw fixation?

Dr. Cicchinelli

In cases where there is severe tissue deficiency I feel an allograft repair is still indicated.

Dr. Fleming

The only indication for me is the patient where their native tissue is not of sufficient strength/quality.

Dr. Hardy

On revision cases and where the native tissue is too attenuated.

Q | Have you ever considered *InternalBrace* ligament augmentation for other indications (Spring Ligament and/or Lateral Ankle with Arthroplasty)?

Dr. Cicchinelli

I have used it for spring ligament repair as part of adult acquired flatfoot reconstruction.

Dr. Fleming

Yes. We are currently exploring its use in acute deltoid reconstruction.

Dr. Hardy

I have used it for spring ligament augmentation, partial syndesmotic injuries and acute deltoid ligament repairs.

Dr. Shibuya

I have used for deltoid repair, arthroscopic anterior tibiofibular ligament rupture repair.

Dr. Todd

I have used it for spring ligament repairs.

Q | What are your thoughts on the *InternalBrace* ligament augmentation repair avulsing the fibula after recovery and return to sports? Specifically if the patient suffers a traumatic inversion/plantar flexion event?

Dr. Fleming

I haven't been concerned about that specifically. I tend to place it superior enough that I don't think it compromises the structural integrity of the lateral malleolus.

Dr. Hardy

I do have this concern. The native tissues should be strong enough to withstand full activity at this point and it also obviates the concern for overtightening and possible avulsion injuries.

Dr. Shibuya

Out of 30 consecutive cases with fibular autograft anchoring with a tenodesis screw, I had two fractures of the fibula. Both patients were overweight males with severe underlying cavus foot deformity.

Dr. Todd

I do not believe this to be possible and have never seen this.

Q | Do you feel there is a downside to implementing *InternalBrace* ligament augmentation on all lateral ankle, Spring and Deltoid repairs?

Dr. Cicchinelli

No, it is an augment that can only add additional stability to native tissue during healing if the native tissue is of sufficient quality.

Dr. Fleming

I don't see any downsides from making this a routine practice. In fact, this has been the foundation for all of soft tissue repairs.

Q | Can you make the *InternalBrace* ligament augmentation repair too tight?

Dr. Fleming

I think you can make it too tight. If you push the talus posteriorly beyond its resting state externally rotate the foot in the mortise you could over constrain the joint.

Dr. Shibuya

Yes, especially when it bridges not only the ankle joint but also the subtalar or mid-tarsal joint (by placing one of the arms into more distal osseous structures), it can be unnaturally tight if not careful.

Dr. Todd

In my experience you can make it too tight.



Lateral Ankle Repair Revolutionized



Please scan QR code for Surgical Technique Animation



Please scan QR code for MN defensive back with bilateral Brostrom with InternalBrace™ ligament augmentation seven weeks post-op.



InternalBrace™ Ligament Augmentation Repair Kit

The Brostrom lateral ankle ligament secondary repair is a proven method for treating a chronic lateral ligament disruption with instability. Since its original description in 1966, certain problematic issues have stimulated the use of augmentation techniques such as the use of the inferior extensor retinaculum, periosteum, and/or tendon transfer for lateral ankle ligament pathologies. The issues for which these augmentations have been designed include the fact that (1) the Brostrom repair needs a fairly extensive period of immobilization and protection to allow the tissue to mature adequately; (2) it does not work well in ligamentous lax patients; (3) patients with associated subtalar instability may require more substantial stabilization; (4) concerns exist regarding the adequacy of the secondary repair in especially large individuals; (5) questionable tissue for repair is often encountered; and (6) there is a 10-20% recorded failure rate over time.

Since all of the described augmentations to date utilize normal tissues in a non-anatomical fashion, we describe a simple augmentation technique that does not violate normal tissue, and protects the ligament repair while it matures.



InternalBrace Ligament Augmentation Repair with Kit (AR-1678-CP) includes:

BioComposite SwiveLock anchor w/#2 FiberTape suture, 3.5 mm
 BioComposite SwiveLock anchor, 4.75 mm
 Guidewire w/ Trocar Tip, 1.35 mm
 Drill Bit, cannulated, 2.7 mm
 Drill Bit, 2.7 mm
 Punch/Tap for 3.5 mm SwiveLock anchor
 Drill Bit, 3.4 mm
 Punch/Tap for 4.75 SwiveLock anchor
 Drill Guide
 Two Free Needles
 Suture Passing Wire

InternalBrace Ligament Augmentation Repair with Collagen Coated FiberTape Suture Kit (AR-1688-CP) Includes:

BioComposite SwiveLock anchor w/#2 Collagen Coated FiberTape suture, 3.5 mm
 BioComposite SwiveLock anchor, 4.75 mm
 Guidewire w/ Trocar Tip, 1.35 mm
 Drill Bit, cannulated, 2.7 mm
 Drill Bit, 2.7 mm
 Punch/Tap for 3.5 mm SwiveLock anchor
 Drill Bit, 3.4 mm
 Punch/Tap for 4.75 mm SwiveLock anchor
 Drill Guide
 Two Free Needles
 Suture Passing Wire
 InternalBrace Ligament Augmentation PEEK

Literature:

InternalBrace Ligament Augmentation Roundtable Brochure LB1-00022-EN
 InternalBrace Ligament Augmentation Repair Product and Technique Highlights LS1-0408-EN
 InternalBrace Ligament Augmentation Repair for Spring Ligament Repair Product and Technique Highlights LS1-0405-EN
 InternalBrace Ligament Augmentation Repair for Deltoid Ligament Repair Product and Technique Highlights LS1-0407-EN

Multimedia:

InternalBrace Ligament Augmentation for Lateral Ankle Instability VID1-00448-EN
 InternalBrace Ligament Augmentation Repair in Conjunction with Open Brostrom Surgical Technique VID1-0492-EN
 InternalBrace ATFL Ligament Augmentation Repair Cadaver Model, May, 2012 VID1-0408-EN
 InternalBrace Ligament Augmentation Repair: Verification of Benefit and Strength of Lateral Ankle Repair VID1-00011-EN
 Flatfoot Reconstruction with Spring Ligament InternalBrace Augmentation and Calcaneal Osteotomy Step Plate Surgical Technique Video VID1-00018-EN
 InternalBrace Ligament Augmentation Repair Presentation: Spring Ligament Surgical Technique, by Jorge Acevedo, MD VID1-0405-EN
 ATFL Talus to Fibula Animation AN1-00145-EN
 ATFL Fibula to Talus Animation AN1-00146-EN
 InternalBrace Ligament Augmentation Repair: Spring Ligament Animation AN1-0003-EN



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