

Features & Benefits

Manufactured from PLDLA poly(L-lactide-co-D, L-lactide)

- Not visible on radiographs
- Will be replaced by bone over time
- Simplifies revisions
- Won't interfere with MRI or CT scans
- Amorphous material is more biocompatible

"Push-in" Implant Design (3 mm and 3.7 mm diameters)

- Superior fixation strength
- Unsurpassed insertional control
- Accommodates plication suture technique
- Primary and revision/backup anchors available

Implant Eyelet is Braided Suture

- Eliminates suture abrasion/breakage
- Accommodates up to two #2 sutures
- Maintains eyelet strength throughout most of the degradation cycle
- Attached suture slides easily through eyelet

Implant Preloaded with #2 Suture

- Enhances suture management
- Provides tissue fixation options

Implant Packaged with Disposable Driver

- Quick and efficient

Two Instruments Required (Drill & Spear)

- Simple two-step insertion

3 mm Implant System

Bio-SutureTak Instrumentation Set includes: (AR-1934S)

Spear Guide	AR-1949
Blunt Obturator for Spear Guide	AR-1949-02
Bio-SutureTak Punch	AR-1934P
Bio-SutureTak Instrumentation Case	AR-1934C

Implants and Disposables:

Bio-SutureTak w/#2 FiberWire	AR-1934BF
Bio-SutureTak	AR-1934B
Bio-SutureTak w/#2 TigerTail	AR-1934BFT
Bio-SutureTak w/two #2 FiberWire	AR-1934BF-2
Bio-SutureTak w/Needles and #2 FiberWire	AR-1934BNF
Plication Driver	AR-1934DBS
Step Drill, 2.4 mm*	AR-1250LT
Spade Tip Drill*	AR-1257

(alternative to AR-1250LT, see technique)

Clear Guide	AR-1934CG
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Bio-SutureTak Disposables Kit (Clear Guide and Drill)	AR-1934DS
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Accessories for Bio-SutureTak with Needles:

Short Spear for Bio-SutureTak w/Needles	AR-1326G
Short Spade Tip Drill	AR-1256

continued on back

3.7 mm Implant System

Bio-SutureTak Instrumentation Set includes: (AR-1934LS)

Spear with Trocar	AR-1907
Bio-SutureTak Instrumentation Case	AR-1934C

Implants and Disposables:

Bio-SutureTak w/#2 TigerTail	AR-1934BLFT
Step Drill, 2.7 mm*	AR-1908

**Instrument sets do not include limited reuse drill.*



Innovative Solutions in Minimally Invasive Orthopaedics

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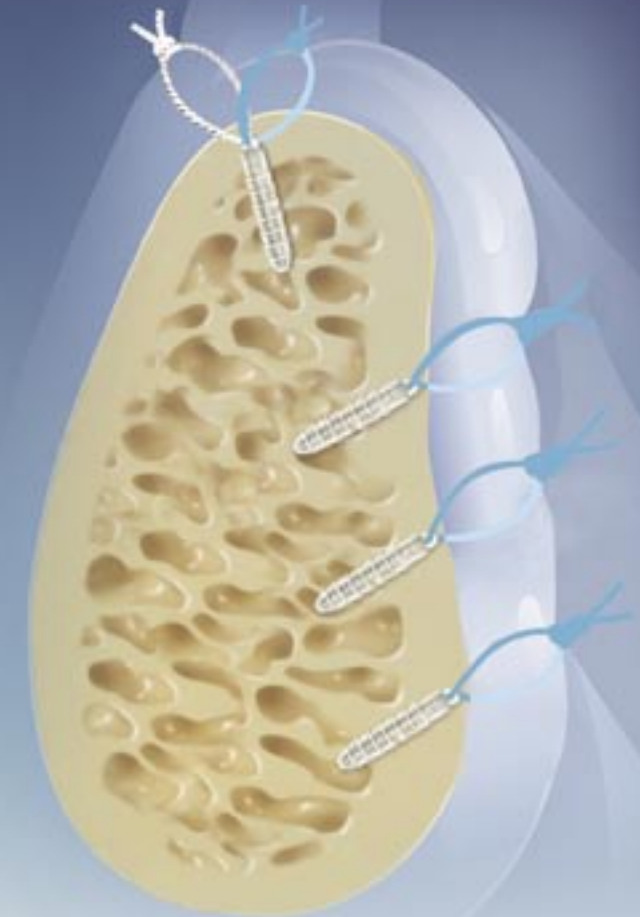
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Bio-SutureTak™ Suture Anchor



The Bio-SutureTak is a bioabsorbable “push-in” suture anchor with a molded-in suture eyelet.

The unique suture eyelet maintains its strength through most of the degradation cycle and eliminates abrasion to attached suture during knot tying. The flexible eyelet eliminates the need to orientate the eyelet during insertion to optimize suture sliding characteristics.

A slotted Plication Driver option allows sutures to be placed in tissue first, then loaded into the anchor prior to fixation to bone if desired.

The Bio-SutureTak is available in 3 mm and 3.7 mm diameters and comes loaded with #2 FiberWire® suture to eliminate suture breakage during knot tying. The primary indication of the 3.7 mm Bio-SutureTak is for revision stability procedures or as a backup when soft bone at the glenoid is encountered.

Simple predrilling and push-in insertion significantly reduces surgery time and preserves bone stock versus other bioabsorbable implants. The implant is manufactured from a noncrystalline copolymer, poly(L-lactide-co D, L-lactide).

Implant Degradation Characteristics

In vitro degradation characteristics were carried out at an independent lab to assess pull-out force measurements, mass change, molecular weight loss, and gross morphological change. The implants underwent degradation in saline at physiological temperature and were assessed at 0, 2, 4, 6, 8, 12 and 16 weeks. These results below reflect ETO sterilization of the Bio-SutureTak.

180 Newtons	177 Newtons
Time Zero	16 Weeks

Pull-out Strength

Simplified Surgical Technique

The 3 mm and 3.7 mm Bio-SutureTaks each have designated instrumentation. The surgical technique is the same for both size implants.

The Spear Guide is inserted through an 8.25 mm diameter translucent Twist-In Cannula and placed over the rim of the glenoid. The sharp trocar is tapped with a mallet to create a shallow pilot hole for the drill. The trocar is removed and the Step Drill introduced through the Spear into the pilot hole. Drill depth is determined by the mechanical depth stop at the rear of the Spear handle. The drill is removed and the Bio-SutureTak implant is introduced through the Spear into the hole. The implant is driven in with light taps of a mallet until the second laser mark is flush with bone. Alternatively, if the laser line just distal to the implant inserter handle is flush with the back of the Spear handle, the implant will be appropriately countersunk. The sutures are freed from the handle and the handled inserter removed with the Spear. For the 3 mm Bio-SutureTak, the Spade Tip Drill can be used as an alternative to the standard 2.4 mm Step Drill when predrilling and implant insertion without the cannulated Spear is desired.



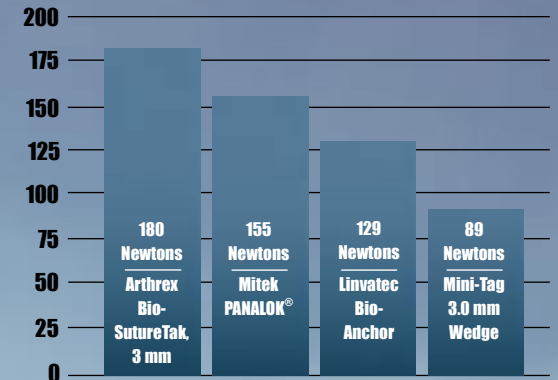
3.7 mm Bio-SutureTak Instrumentation

3 mm Bio-SutureTak Instrumentation

Pull-Out Strength

The design of the Bio-SutureTak Suture Anchor on average provides 180 Newtons of pull-out strength. The chart below shows the pull-out force in Newtons needed to fail the Arthrex Bio-SutureTak compared to other similar size bioabsorbable implants.

Implant Comparison



The 3 mm Bio-SutureTak was tested in 20 lb foam block at an independent lab. The pull-out strength data for the comparison products was published by F. Alan Barber, M.D.



Actual size of the 3 mm Bio-SutureTak Suture Anchor



Actual size of the 3.7 mm Bio-SutureTak Suture Anchor