Value Analysis Brief—
HEALIX ADVANCE™ KNOTLESS Anchor

Introduction

This value analysis brief presents information on the design features and clinical benefits of using the DePuy Synthes Mitek Sports Medicine HEALIX ADVANCE™ KNOTLESS Anchor. This anchor provides knotless fixation for rotator cuff repair and biceps tenodesis repairs. The HEALIX ADVANCE KNOTLESS Anchor design incorporates the following features: independent cortical and cancellous threads to maximize fixation; multi-thread design for fast anchor insertion; and an enclosed and protective distal tip to aid in anchor alignment and usability. In addition to these design features, the HEALIX ADVANCE KNOTLESS Anchor also includes a novel sliding suture cleat management system for repair tensioning and a sliding #2 ORTHOCORD® High Strength Suture for a stay suture. The referenced data for the background section were obtained through a search of MEDLINE for current trends in arthroscopic repair procedures for patients with rotator cuff tears. The referenced data supporting the clinical value proposition of the HEALIX ADVANCE KNOTLESS Anchor were obtained from a recently completed biomechanical study performed by Mitek Sports Medicine. The results of this study have yet to be published.

Background

A rotator cuff tear is a common cause of pain and disability among adults. In 2008, about 2 million people in the United States visited their doctors because of a rotator cuff problem. Surgical repair of the rotator cuff is aimed at anatomic restoration of the rotator cuff and the head of the humerus to reduce pain, improve motion, restore joint function, and improve the general health status of the patient. Surgical rotator cuff repair has evolved from the classic open approach to a mini-open (or deltoid-sparing) approach, and then finally to an all-arthroscopic repair approach. The arthroscopic approach decreases the pain associated with cuff repair, avoids the complications related to deltoid reattachment, and optimizes the rehabilitation process.

Disorders of the long head of the biceps tendon, such as biceps tendonitis, are commonly associated with rotator cuff tears. Biceps tenodesis describes the surgical procedure that is usually performed for the treatment of biceps tendinitis of the shoulder. Arthroscopic rotator cuff repair may be combined with biceps tenodesis to treat both pathological processes simultaneously.

The evolution to the arthroscopic approach for rotator cuff repair has been driven by the development and availability of arthroscopic instrumentation specifically designed for soft tissue repair techniques. One of the special implants used in arthroscopic repair of the rotator cuff is the knotless suture anchor. Double-row rotator cuff repairs performed with a “suture bridging” technique typically use knotless suture anchors for the lateral-row fixation. A variety of threaded (screw-in) and non-threaded (push-in) knotless anchor designs exist which hold sutures through friction between the anchor and adjacent bone. Additionally, a variety of anchor materials exist including metal, polyetheretherketone, biodegradable non-osteocducive materials, and biodegradable biocomposite materials.

Mitek Sports Medicine recently launched the HEALIX ADVANCE KNOTLESS Anchor. This anchor has been designed in the image of the HEALIX ADVANCE Family of Anchors, and delivers knotless fixation for rotator cuff and biceps tenodesis repairs. The HEALIX ADVANCE KNOTLESS Anchor features a number of design elements that translate into procedural and clinical benefits for the surgeon and patient. These design features and clinical benefits are summarized below.

Design Features

Optimized Material and Sizes

The HEALIX ADVANCE KNOTLESS Anchor features two choices for materials: BIOCRYL™ RAPIDE™ Biocomposite Material and radiolucent polyetheretherketone (PEEK). BIOCRYL RAPIDE Biocomposite Material consists of 30% osteoconductive β-TCP and 70% poly-lactide co-glycolide (PLGA). Pre-clinical studies have shown that anchors composed of BIOCRYL RAPIDE Biocomposite Material have improved strength as well as more favorable absorption characteristics compared to anchors composed of earlier polymer and biocomposite materials.
The HEALIX ADVANCE KNOTLESS Anchors are available in three size options: 4.75mm, 5.5mm, and 6.5mm. These size options can address a multitude of bone qualities and patient demographics.

**Optimized Anchor Body Design**

The HEALIX ADVANCE KNOTLESS Anchor features a dual-thread design with independent cortical and cancellous threads to maximize fixation and to provide the surgeon with confidence of a secure fixation.

![HEALIX ADVANCE KNOTLESS Anchor](image)

The multi-thread design allows for a faster and more aggressive insertion. The anchor also features an enclosed and protective “can’t miss tip” to aid in anchor alignment and usability.

The HEALIX ADVANCE KNOTLESS Anchor has several advantages in anchor body design relative to competitors such as the Arthrex® SwiveLock® and PushLock® Anchors. For example, the proximal cortical threads unique to the HEALIX ADVANCE KNOTLESS Anchors maximize fixation of the suture in the harder and more dense cortical bone layer whereas SwiveLock® and PushLock® do not provide variable cortical and cancellous bone interaction.

![HEALIX ADVANCE KNOTLESS, SwiveLock®, and PushLock® Proximal Anchor Geometry](image)

The HEALIX ADVANCE KNOTLESS Anchor has the same amount of fixation points (4) on one side of the anchor as the SwiveLock® and PushLock® Anchors have on both sides of the anchor combined (4). Additionally, the thread diameter of the HEALIX ADVANCE KNOTLESS Anchors increases slightly at the proximal end of the anchor by 0.25mm. For example, the diameter of the 4.75mm HEALIX ADVANCE KNOTLESS Anchor increases from 4.75mm to 5.0mm at the proximal end of the anchor. This “cortical flare” provides additional compression of the suture in cortical bone when compared to other anchors with constant diameters.

The HEALIX ADVANCE KNOTLESS Anchors are 1-piece devices comprised of a threaded anchor body that lock the suture between the anchor and bone on one side of the anchor. The SwiveLock® and PushLock® anchors utilize a 2-piece design comprised of a threaded [SwiveLock®] or ribbed [PushLock®] proximal anchor body and a distal eyelet.

![Anchor Distal Tips of Fully Inserted HEALIX ADVANCE KNOTLESS, SwiveLock®, and PushLock® Anchors](image)

After insertion, the suture is routed along one side of the proximal anchor body, through the distal eyelet, and back along the other side of the anchor body. The SwiveLock® and PushLock® distal eyelets are not locked or constrained axially against the proximal anchor body when the devices are inserted (there is generally a 2-3mm gap between the anchor body and distal eyelet). Therefore, these anchors only provide “1-sided fixation” during initial suture slippage; “2-sided fixation” of the suture occurs after the distal eyelet moves proximally and contacts the anchor body. Once the distal tip comes into contact with the anchor body, only then can the suture slide past both sides of the anchor body in two-sided fixation.

In addition, there is a risk that the distal eyelet on the PushLock® Anchor may migrate away from the anchor body after insertion. The PushLock® Anchor distal eyelet tip is made from titanium in order to penetrate bone without the use of an awl. If suture slippage occurs and the distal tip travels up to meet the anchor body, the PushLock®-SP titanium tip could be free to migrate around the anchor body and out of the
bone, if the bone quality is poor enough to allow this.

**Optimized Suture Configurations and Stay-Stitch Suture**

The HEALIX ADVANCE KNOTLESS Anchor will accommodate up to 6 tails of #2 ORTHOCORD® High Strength Orthopaedic Suture. The surgeon can pull 4 tails of ORTHOCORD High Strength Suture in at one time. The HEALIX ADVANCE KNOTLESS Anchors also include a sliding #2 ORTHOCORD High Strength Suture for a stay suture. This feature provides versatility for the surgeon (i.e., can slide to remove after the repair is finished or incorporate Stay-Stitch into repair to address a dog-ear and be able to tie a sliding knot).

**Optimized Inserter Shaft**

The HEALIX ADVANCE KNOTLESS Anchor contains a fully slotted inserter shaft.

**HEALIX ADVANCE KNOTLESS Anchor Inserter Shaft**

This fully slotted inserter shaft improves usability for the surgeon.

**Optimized Ring**

The HEALIX ADVANCE KNOTLESS Anchor features a novel sliding suture cleat management system to facilitate suture alignment and tensioning and to prevent suture wrapping. The ring ensures that all sutures remain in-line inside the inserter shaft as the anchor advances. The 360°Cleats enable surgeons to individually tension each stitch and “dock” them to maintain the desired tension during tensioning. The ring also prevents any suture wrapping inside the cannula or down by the anchor and also automatically unwinds stitches that wrapped outside of the cannula as the inserter is removed.

**Clinical Benefits**

**The HEALIX ADVANCE KNOTLESS Anchor Promotes Excellent Fixation Strength and Anchor Pullout Strength**

Recently, Mitek Sports Medicine undertook a comparative study to evaluate the biomechanical properties of the HEALIX ADVANCE KNOTLESS Anchor and its major competitors: Arthrex® SwiveLock® and PushLock® Anchors, BioMet® ALLThread™ Knotless, and Smith & Nephew FOOTPRINT™ Ultra. These anchors are similar in that each locks suture between anchor and bone and their primary failure mode is suture slippage. The performance of these anchors was evaluated by measuring the suture fixation strength to 3mm suture slippage (3mm of gap formation), as well as the ultimate failure load (anchor pullout strength). A suture slide of 3mm is considered a clinical failure. All anchors were inserted into biomimetic foam blocks with similar cortical and cancellous layer densities to carry out a repeatable and reproducible anchor performance test. For each sample, the data recorded were the peak force between 0.0-3.0mm suture slide, as well as the ultimate failure load (in lbs). The results of this study are presented below for the HEALIX ADVANCE KNOTLESS PEEK Anchor (Figure 3) and for the HEALIX ADVANCE KNOTLESS Anchor used with BIOCRYL RAPIDE Biocomposite Material (Figure 4).

**Figure 3. Anchor Fixation Strength for HEALIX ADVANCE KNOTLESS PEEK Anchors and Competitors**

![4.5mm & 4.75mm PEEK Anchor Fixation Strength](image_url)

![5.5mm PEEK Knotless Anchor Fixation Strength](image_url)
The results indicate that the HEALIX ADVANCE KNOTLESS PEEK Anchors showed equivalent to or better results when compared to the Arthrex® SwiveLock® and PushLock® anchors, BioMet ALLThread Knotless anchor, and the Smith & Nephew Footprint Ultra anchor in terms of suture slide to clinical failure (3mm of suture slide) as well as ultimate load to failure (anchor pullout strength) for the 4.5mm/4.75mm size range and 5.5mm size. 7,8 Suture slide was the failure mode observed in all anchors, because a nominal foam model was chosen.

**Conclusion**

Overall, the HEALIX ADVANCE KNOTLESS Anchor has been designed in the image of the HEALIX ADVANCE Family of Anchors and delivers knotless fixation for rotator cuff and biceps tenodesis repairs. These design features include an optimized anchor body (i.e., independent cortical and cancellous threads to maximize fixation as well as multi-thread design for fast anchor insertion), an enclosed and protective distal tip to aid in anchor alignment and usability, a novel sliding suture cleat management system for repair tensioning, two material options - PEEK or BIOCRYL RAPIDE Biocomposite Material, three size options to address a multitude of bone qualities and patient demographics, a sliding#2 ORTHOCORD High Strength Suture for a stay suture, and up to 6-suture compatibility. These design features translate into clinical benefits for the surgeon and patient. The results of a recent biomechanical study confirm that the HEALIX ADVANCE KNOTLESS Anchor offers equivalent to or better fixation strength and anchor pullout strength when compared to other competitor anchors on the market.

**Citations**

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