Summary

Adjustability: The ReelX STT is designed to provide patient-Specific Tissue Tensioning (STT) and adjustable contact pressure at the repair site using a built-in “reeling” mechanism.

Strength: With a barbed PEEK outer shell that is designed to expand during “reeling” as well as an eyelet that passes the suture through the anchor body, the ReelX STT exhibits excellent fixation strength compared to competitive knotless anchors.23

Ease of Use: The ReelX STT was designed for ease of use, with a sharp metal self-punching tip and unique design that allows the anchor to be inserted and deployed by the surgeon alone without the need for assistance.

Introduction

Rotator cuff tendon repair poses significant clinical challenges, both to securely attach the ruptured tendons to the humerus and to allow for tendon-bone healing. In patients with massive cuff tears, re-tear rates ranging from 30 to 94% have been reported.1-7 Repair strategies and implant technologies are continually evolving with the goal of enabling surgeons to achieve a more stable repair while making the surgical procedure less technically demanding. It is believed that improved initial tendon fixation may improve tendon-bone healing, potentially leading to improved clinical outcomes.5

In response to the clinical need for repair strength, adjustability, and surgical ease of use, Stryker has developed the ReelX STT Knotless Suture Anchor with a novel suture reeling mechanism designed to provide surgeons with the ability to apply patient-Specific Tissue Tensioning (STT) and adjustable contact pressure at the rotator cuff footprint.
Cuff Anatomy and Surgical Repair

The rotator cuff consists of four tendons – the supraspinatus, infraspinatus, and teres minor tendons attach to the greater tuberosity of the proximal humerus, while the subscapularis tendon attaches to the lesser tuberosity (Figure 1). These tendons stabilize the shoulder joint and enable arm abduction and rotation.

- Repair of torn rotator cuff tendons involves re-attaching the torn ends to their original footprint on the humerus using high strength sutures and suture anchors that are implanted into the bone.

- Success of the repair may be limited by the extent of tendon healing to bone, and may potentially be improved by enhancing mechanical fixation and tendon contact with bone at the footprint.7

Figure 1.
Posterior view of the rotator cuff showing the supraspinatus, infraspinatus, and teres minor tendons and muscles.

Figure 2.
Full thickness tear of the supraspinatus tendon revealing tendon footprint on the greater tuberosity.

The Role of Tendon-Bone Healing in Cuff Repair

The goal of rotator cuff repair is to provide sufficient fixation and stability, with minimal gap formation, until biological healing between the tendons and the underlying bone can occur.8-10 Improving the outcome of cuff repairs may require repair strategies that promote tendon-bone healing.11

Factors that may affect healing and clinical outcome include:7,16
- Strength and stability of the repair
- Slippage of sutures, anchors, or knots leading to gap formation
- Footprint contact area and pressure
- Quality of the tendon, muscle, and bone
- Size of the tear
- Biochemical signaling
- Rehabilitation regimen

A secure repair that minimizes gap formation and interface motion may allow for tendon healing and improved clinical outcome.12,13 It has been shown that the integrity of the repaired cuff tendons is associated with improved postoperative function and strength.3,12,14,15
The ReelX STT Knotless Suture Anchor has been designed for Adjustability, Strength, and Ease of Use

Adjustability

Controlling Contact Pressure at the tendon footprint may minimize gap formation

Tendon-bone healing may potentially be enhanced by restoring the native footprint and providing adequate contact pressure or compression at the repair site.8,11,17,18

The optimal level of pressure has not yet been determined, and is dependent on surgeon preference and repair technique.

An appropriate amount of compression may minimize motion between the tendon and bone, potentially improving the healing process.1

• Insufficient pressure may reduce the contact between tendon and bone resulting in gap formation.1
• Excessive pressure may disrupt blood supply in the tendon.1

With a lock position after every 60 degrees of rotation and approximately 10mm of Force Fiber wound within the anchor with each 360 degree turn, the ReelX STT anchor is designed to enable adjustable contact pressure at the tendon footprint.

In addition, the versatile handle can be re-inserted into the anchor to apply additional tension after deployment.

The ReelX STT knotless suture anchor is specifically designed to provide surgeons with control over the level of tension and pressure applied at the repair site by reeling the high strength Force Fiber suture within the anchor.

Fixation Strength

Anchor expansion and suture fixation promote fixation strength

Anchor expansion shown to increase fixation strength24

The ability of suture anchors to achieve strong fixation is important to the success of the repair, and the quality of bone is one of the factors that may affect tendon-bone healing.16

The ReelX anchor was designed with an expansion mechanism for enhanced fixation. As suture is reeled into the anchor, the PEEK anchor body expands (Table 1).

Expansion of ReelX STT has been shown to increase anchor pull-out strength.24

<table>
<thead>
<tr>
<th>Turn #</th>
<th>Anchor Diameter (mm)</th>
<th>Max Load (lbf)</th>
<th>Max Load (N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>6.0 ± 0.04</td>
<td>56 ± 3</td>
<td>250 ± 15</td>
</tr>
<tr>
<td>3</td>
<td>6.6 ± 0.1</td>
<td>69 ± 10</td>
<td>310 ± 50</td>
</tr>
</tbody>
</table>

Table 1. Anchor diameter and maximum load of ReelX STT anchors in 20 pcf foam after 1 and 3 reel rotations.24 ReelX anchors were inserted into 20 pcf foam blocks and the tensioning knob was turned for one or three complete revolutions. Anchors were loaded at 90º to the surface of the foam.
**Suture fixation is important to repair stability**

Several knotless anchor designs pinch the suture between the anchor and bone, relying on friction to prevent the suture from slipping.

- Suture fixation potentially may be affected by bone quality.
- Forces may not be distributed to the anchor, and may lead to the suture cutting through the bone.

The ReelX STT anchor was designed with two eyelets:

- The distal eyelet allows the suture to pass through the body of the anchor, and was designed to both distribute load to the anchor body and to lock the suture via the reeling mechanism.
- The proximal eyelet was designed to prevent the suture from cutting through bone during cyclic loading.

Minimizing suture slippage is important for maintaining the stability of the repair.

- The ReelX STT was designed with an internal locking mechanism to minimize suture slippage.
- After 500 cycles of loading, only approximately 370 μm of average displacement was observed with the ReelX anchor in foam.

The ReelX STT anchor exhibits a maximum tensile load that is statistically greater than all competitive anchors tested (Figure 3) and load at 3mm of displacement, which has been defined as clinical failure, that is statistically greater than half of the competitive anchors tested (Figure 4).

**Ease of Use**

**Self-Punching Tip and Two-Hand Operation**

The ReelX STT anchor has a sharp, self-punching metal tip, which is designed to allow for insertion of the anchor without the use of separate instrumentation. Formation of a pilot hole is optional for hard bone.

Most knotless suture anchor designs require assistance for anchor insertion, tensioning, and deployment. The ReelX STT was designed for use with only two hands in order to facilitate the repair.

The ReelX STT was designed with ease of use in mind in order to increase precision in repair tensioning while increasing OR efficiency.

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**Figure 3. Maximum load**, average ± standard deviation, *p<0.0001**

**Figure 4. Load at 3mm Displacement**, average ± standard deviation, *p<0.02**

*Each anchor (n=6) was inserted into 12.5 pcf cellular foam with a 20 pcf cortical shell according to each manufacturer’s instructions and using the indicated instruments and high strength suture from each manufacturer. Loading direction was at 20° with respect to the foam surface, and anchors were cyclically loaded for 500 cycles before being loaded to failure. Statistical differences were determined using a one-way ANOVA followed by Tukey HSD post-hoc tests for pair-wise comparisons.*
ReelX STT
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The ReelX STT Knotless Suture Anchor has been designed for Adjustability, Strength, and Ease of Use

Adjustability
Specific Tissue Tension: Central reel with integrated eyelet winds suture within the anchor, expanding the outer diameter and enabling surgeons to apply adjustable tension to their cuff repairs.

Versatile Inserter: Designed to be re-inserted into the anchor to re-activate the reeling mechanism, providing surgeons with the ability to apply additional tension after anchor deployment and after the sutures have been cut.

Anchor and Suture Fixation Strength
Expandable PEEK Outer Shell: Barbed PEEK shell designed to expand during tensioning and to enhance fixation under cortical bone.

Distal and Proximal Eyelets: Distal eyelet through anchor body designed to distribute load to the anchor and to allow the suture to be reeled into the anchor. Proximal eyelet designed to prevent suture from cutting through bone.

Ease of Use
Self-Punching: Sharp metal tip facilitates anchor insertion into bone without instrumentation (instrumentation optional).

Two-Hand Operation: Anchor designed to be inserted, deployed, and tensioned without the need for assistance.

<table>
<thead>
<tr>
<th></th>
<th>Stryker ReelX STT</th>
<th>Depuy Mitek VERSALOK&lt;sup&gt;1&lt;/sup&gt;</th>
<th>Arthrex PushLock SP&lt;sup&gt;2&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Versatility in suture configurations</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Self-Punching</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Internal suture fixation instead of friction between anchor and bone</td>
<td>✓</td>
<td>✓</td>
<td>X</td>
</tr>
<tr>
<td>Tension control after anchor deployment</td>
<td>✓</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Expandable outer shell with barbs designed to improve fixation strength</td>
<td>✓</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>
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References:
A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

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