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510(k) SUMMARY

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SUBMITTED BY:

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CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME

Classification Name:	Fastener, fixation, nondegradable, soft tissue
Common/Usual Name:	Soft Tissue Anchor
Proprietary Name:	Stabilizer™ Soft Tissue Anchor

PREDICATE DEVICE

Mitek Superanchor™ manufactured by Mitek Surgical Products, Inc.

DEVICE DESCRIPTION

The Stabilizer Soft Tissue Anchor is a 316L Stainless Steel implant designed to provide an attachment means for soft tissue to bone using USP grade surgical sutures in joint reconstruction procedures. It is available in two sizes: 5 and 8 mm diameter. Attachment is accomplished by drilling an appropriately sized hole in uncompromised bone with a specifically designed drill, inserting the soft tissue anchor into the bone, expanding the stabilizer teeth of the implant to secure the anchor into bone using the anchor inserter, and securing soft tissue to the implanted anchor by using three sutures. The anchor inserter (which spreads the stabilizer teeth of the implant) also serves as a suture organizer for delivery of sutures to the implant site during the implantation procedure. A crimper is also included to help secure the suture of choice to the Stabilizer and to prepare the stabilizer for entry into the predrilled hole.

INDICATIONS FOR USE:

The Stabilizer Soft Tissue Anchor is intended for use with USP Sutures as an attachment means for soft tissue and bone for the indications listed below:

Shoulder
1. Bankart repair
2. SLAP lesion repair
3. Acromioclavicular separation
4. Rotator cuff repair

Elbow
1. Tennis elbow repair
2. Biceps tendon reattachment
3. Medial and lateral repairs

Shoulder
(continued)

5. Capsule shift\capsulolabral reconstruction
6. Biceps tenodesis
7. Deltoid repair

Ankle

1. Lateral instability
2. Medial instability
3. Achilles tendon repair/ reconstruction

Knee

1. Extra-capsular repairs and attachment of:
   - medial collateral ligament
   - lateral collateral ligament
   - posterior oblique ligament and joint capsule to tibia
   - joint capsule closure to the anterior proximal tibia
2. Extra-capsular reconstruction, ITB tenodesis
3. Patellar ligament and tendon avulsions repairs

CONTRAINDICATIONS, WARNINGS, PRECAUTIONS AND COMPLICATIONS

1. Contraindications

The Stabilizer Soft Tissue Anchor is contraindicated in the presence of pathological conditions such as severe osteopenia, cystic degeneration, or comminution of bone which would compromise fixation. The Stabilizer should not be used in compromised bone or in the presence of pathological soft tissue conditions which would compromise fixation. It should also not be used in the presence of pathophysiological conditions such as infection, osteonecrosis, or bone disease. The product should not be used in patients with known allergies to stainless steel.

2. Warnings

2.1 The Stabilizer Soft Tissue Anchor is intended to assist in the fixation of soft tissue to bone. Each case should be carefully analyzed to assure that the appropriate sized anchor and suture are being used and that the appropriate number of anchors are present to support the reconstruction. Excessive tension on the suture or anchor may result in suture breakage or implant pull-out from the bone. In some cases, revisions may require explant of the bone anchor.

2.2 The drill is stainless steel. To assure proper bone cutting characteristics, the drill should be replaced after every 10 uses. If the drill should break during use, remnants should be removed from the surgical site prior to proceeding.

3. Precautions

The Stabilizer Soft Tissue Anchor is intended for use by surgeons familiar with soft tissue and bone attachment techniques. The patient must be cautioned against early weightbearing and/or premature ambulation as this could lead to loosening or failure of the implant or suture attachments. Standard postoperative practices for the treatment and rehabilitation of repaired joints must be followed.

4. Complications

Potential complications with the The Stabilizer Soft Tissue Anchor include, but are not limited to, the following: infection, osteomyelitis, suture breakage, implant breakage, implant pull-out, reoperation, revision or explant.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The product design, material of construction, and function as a soft tissue anchor is substantially equivalent to the FDA cleared predicate device.