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510(k) SUMMARY

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, 8 mm

PREDICATE DEVICE

Mitek Ligament Anchor manufactured by Mitek Surgical Products, Inc.

DEVICE DESCRIPTION

The Stabilizer Soft Tissue Anchor is a 316L stainless steel implant intended for use with USP Sutures as an attachment means for soft tissue and bone in Anterior Cruciate Ligament (ACL) repair or reconstruction. Stabilizer instruments must be used to install the Stabilizer Soft Tissue Anchor.

Stabilizer placement 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 the ACL 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 a 316L stainless steel implant intended for use with USP Sutures as an attachment means for soft tissue and bone in Anterior Cruciate Ligament (ACL) repair or reconstruction. Stabilizer instruments must be used to install the Stabilizer Soft Tissue Anchor.

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 anchor and suture are appropriate to support the repair/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.