



WRIGHT
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510(k) Summary

Contact Person: Cristie Manuel
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Trade/Proprietary Name: ANCHORLOK™ II Soft Tissue Anchor System
 Common Name: Fastener, fixation, nondegradable, soft tissue
 Product Classification: Class II
 Predicate Device: ANCHORLOK™ Polyester Suture Soft Tissue Anchor System

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

Description/Intended Use

The ANCHORLOK™ II Soft Tissue Anchor System is a single use, sterile kit consisting of a bone anchor with a disposable wire leader and disposable protective sleeve. The surgeon uses suture according to preference. The anchor is manufactured from titanium alloy.

The ANCHORLOK™ II Soft Tissue Anchor System is indicated for the following:

- repair of shoulder instability secondary to Bankart lesion, rotator cuff tear, a SLAP lesion, acromioclavicular separation, biceps tenodesis, deltoid tear/separation, or capsular shift or capsulolabral reconstruction;
- repair of elbow instability secondary to biceps tendon detachment, tennis elbow, or ulnar or radial collateral ligament tear/separation;
- repair of hand/wrist instability secondary to tear or separation of the scapholunate ligament, ulnar collateral ligament, or radial collateral ligament;
- repair of knee instability secondary to tear or separation of the medial collateral ligament, lateral collateral ligament, patellar tendon, or posterior oblique ligament, or secondary to iliotibial band tenodesis;
- repair of foot/ankle instability secondary to tear or separation of the Achilles tendon, lateral stabilization tendons/ligaments, medial stabilization tendons/ligaments, midfoot tendons/ligaments, or metatarsal tendons/ligaments

Testing Summary

The 7.5mm anchor was tested according to *Draft Guidance Document for Testing Bone Anchor Devices*, April 1, 1993. The conclusion from this test is that the 7.5mm anchor can be expected to meet or exceed the *in vivo* performance of the 5.0mm anchor.

The 2.5mm and 7.5mm ANCHORLOK™ II Soft Tissue Anchors were tested according to *Draft Guidance Document for Testing Bone Anchor Devices*, April 1, 1993. The conclusion from this test is that the *in vivo* performance of Nylon™ monofilament sutures meets or exceeds the values established by USP for these devices.