# SutureTech, Inc. All-Suture Dual Anchor System INSTRUCTIONS FOR USE

## DESCRIPTION
The **SutureTech All-Suture Dual Anchor** is designed to fixate soft tissue to bone. The system includes UHMWPE all-suture anchors with a set of universal instruments to accommodate varying patient anatomy. The **SutureTech All-Suture Dual Anchor** implants and instruments are provided EO sterilized for single use only.

## MATERIALS
Ultra-high Molecular Weight Polyethylene

## INDICATIONS
The **SutureTech All-Suture Dual Anchor** implants are intended to be used for fixation of soft tissue to bone in the shoulder, foot/ankle, knee, hand/wrist, elbow, and hip in the following procedures:

Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Repair.

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-Foot Reconstruction, Metatarsal Ligament Repair, Digital Tendon Transfers.

Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis.

Hand/Wrist: Scapholunate Ligament Reconstruction, Repair/Reconstruction of Collateral Ligaments, Carpal Ligament Reconstruction, Repair of Flexor and Extensor Tendons at the PIP, DIP, and MCP Joints for all Digits, Digital Tendon Repairs.

Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction.

Hip: Capsular Repair, Acetabular Labral Repair, Gluteal Tendon Repair.

## CONTRAINDICATIONS
Contraindications include but are not limited to:
1. Insufficient quantity or quality of bone.
2. Blood supply limitations and previous infections which may retard healing.
3. Foreign-body sensitivity. Where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantation.
4. Any active infection or blood supply limitations.
5. Conditions that tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period.
6. Do not use for surgeries other than those indicated.
7. Pathological conditions of the bone that would compromise secure anchor fixation.
8. Pathological conditions in the soft tissues to be attached that would impair secure fixation by the suture.

## POTENTIAL ADVERSE EVENTS
1. Infections, both deep and superficial.
2. Foreign body reactions.
3. Allergic reaction.
4. Mild inflammatory reaction.

## WARNINGS
- Contents are sterile unless package is opened or damaged. Do not use any device that has been used, or if the package appears damaged, tampered with or breached.
- For single use only. An internal fixation device must never be reused.
- Do not re-sterilize or reuse any anchor or single-use instrument.
- Postoperatively and until healing is complete, fixation provided by this device should be considered as temporary and may not withstand weight bearing or other unsupported stress. The fixation provided by this device should be protected. The postoperative regimen prescribed by the physician should be strictly followed to avoid adverse stresses applied to the device.
- It is the surgeon's responsibility to be familiar with the appropriate surgical techniques prior to use of this device.
- Incomplete anchor insertion may result in poor anchor performance.

## PRECAUTIONS
- Surgeons should be familiar with the implant, instruments, and surgical technique before implanting this device.
- Prior to use, inspect the device to ensure it is not damaged. Do not use a damaged device.
- Prior to use, inspect the instruments to ensure they are not damaged. Do not use a damaged instrument.
- Implantation of the anchor requires preparation of the insertion site. Only prepare the site with the SutureTech Awl and Inserter Guide.
- Postoperative care is important. A patient should be instructed on the limitations of the implant and should be cautioned regarding weight bearing and body stresses on the appliance prior to secure bone healing.
- Maintain positioning of the Inserter Guide when removing and inserting Awl or Inserter.

## STERILIZATION
The **SutureTech All-Suture Dual Anchor** implants and instruments are provided sterile via EO sterilization.

**Do not re-sterilize.** STERILE EO

## MRI COMPATIBILITY
MR



The **SutureTech All-Suture Dual Anchor** implant is MR Safe.

## FURTHER INFORMATION
Never re-use a **SutureTech All-Suture Dual Anchor** implant under any circumstances.

The surgical technique contains further information on the **SutureTech All-Suture Dual Anchor** device and may be obtained by contacting SutureTech, Inc.

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℞ Only