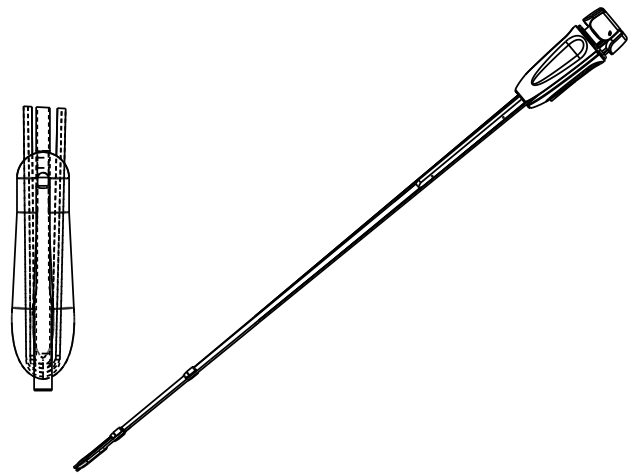
SIRONIX

Arthroscopy Solutions

STATIV®

All Suture Anchor

Product Instructions for Use (IFU) Booklet



STATIV®: IFU V03 | Date : 01/NOV/2021

STATIV® ALL SUTURE ANCHOR

1. DEVICE DESCRIPTION

The SIRONIX® STATIV® All Suture Anchor is a fixation device intended to provide secure fixation of soft tissue to bone. It consists of a soft suture anchor with attached non-absorbable suture(s) to an inserter with handle. The anchors are available in various sizes, preloaded in suture, tape or suture – tape combinations. This device is provided sterile, for single use only.

MATERIAL

Anchor : Non - absorbable suture anchor-braided, UHMWPE
(Ultra-high-molecular-weight polyethylene)
Suture : Braided, UHMWPE non-absorbable #2 Suture.
Tape : Braided, UHMWPE non-absorbable 1.5 mm flat tape
(Refer to individual suture anchor product labels for suture /tape size, type and quantities)
Handle : ABS plastic
Shaft of inserter : Stainless steel

2. INDICATIONS FOR USE

The SIRONIX®STATIV® All Suture Anchors are intended to be used for suture or tissue fixation in the foot, ankle, knee, hand, wrist, elbow, shoulder, and hip for the following indications:

1. **Shoulder :** Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Capsular Shift, and Capsulolabral Reconstruction
2. **Foot/Ankle :** Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Mid-foot Reconstruction, Hallux Valgus Reconstruction, Metatarsal Ligament Repair, and Digital Tendon Transfers
3. **Knee :** Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Iliotibial Band Tenodesis, and Joint Capsule Closure
4. **Hand/Wrist :** Scapholunate Ligament Reconstruction, Digital Tendon Transfers, and Carpometacarpal joint arthroplasty (basal thumb joint

arthroplasty)

5. **Elbow :** Biceps Tendon Reattachment, Ulnar/Radial Collateral Ligament Reconstruction and Lateral Epicondylitis Repair .
6. **Hip :** acetabular labral repair, Capsular repair

3. CONTRAINDICATIONS

1. Known active infections.
2. Known hypersensitivity to the implant material. Where material sensitivity is suspected, appropriate tests should be performed and sensitivity ruled out prior to implantation;
3. Pathological conditions of bone, such as cystic changes or severe osteopenia, which would compromise secure anchor fixation.
4. Pathological conditions in the soft tissues to be attached that would impair secure fixation by suture.
5. Comminuted bone surface, which would compromise secure anchor fixation.
6. Procedures other than those listed in the INDICATIONS section.
7. Physical conditions that would eliminate or tend to eliminate adequate implant support or retard healing, i.e. blood supply limitation, previous infection, etc.
8. Conditions which tend to limit the patient's ability to restrict activities or follow directions during the healing period.
9. The anchor is not designed for and should never be used to attach artificial ligaments.

4. WARNINGS

Do not use if package is damaged. Do not use if the product sterilization barrier or its packaging is compromised.

1. Contents are sterile unless package is opened or damaged. DO NOT RESTERILIZE. For single use only. Discard any open, unused product. Do not use after the expiration date.
2. It is the surgeon's responsibility to be familiar with the appropriate surgical techniques prior to use of this device.

3. Read these instructions completely prior to use.
4. Only use the recommended drill bits and drill guides intended for use with the SIRONIX® STATIV® All Suture Anchor. Improper use of the instruments may injure the patient, damage the instruments, or compromise fixation.
5. Maintaining guide alignment throughout drilling is required to ensure drill hole integrity
6. Do not attempt to implant this device within cartilage epiphyseal growth plates of non-osseous tissue.
7. Do not resterilize or reuse anchors, sutures and insertion devices packaged with the anchor.
8. Incomplete anchor insertion may result in poor anchor performance.
9. Breakage of the suture anchor can occur if the insertion site is not prepared with appropriate instrumentation prior to implantation.
10. Postoperatively and until healing is complete, fixation provided by this device should be considered as temporary and may not withstand weight bearing or this device should be protected. The postoperative regimen prescribed by the physician should be strictly followed to avoid adverse stresses applied to the device.
11. Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure. Device removal should be followed by adequate postoperative management.
12. Detailed instructions on the use and limitations of the device should be given to the patient.
13. This is a single use device. Reuse of this device could result in failure of the device to perform as intended and could cause harm to the patient and/or user.
14. Patient sensitivity to the device materials should be considered prior to Implantation. See adverse effects.
15. **Biohazard waste**, such as explanted devices, needles and contaminated surgical equipment, should be safely disposed of in accordance with the institutions policy.

5. PRECAUTIONS

1. Hazards associated with reuse of this device include, but are not limited to, patient infection and/or device malfunction.
2. Prior to use, inspect the device to ensure it is not damaged. Do not use a damaged device.
3. Postoperative care is important. Instruct the patient on the limitations of the implant and caution them regarding weight bearing and body stresses on the appliance prior to secure bone healing.
4. Regulations restricts this device to sale by or on the order of aphysician
5. Do not use sharp instruments to manage or control the suture
6. As with any suture anchor or suturing technique, the fixation given should be considered as only temporary, until biological attachment of tissue to bone is completed, and may not withstand weight bearing or other unsupported stresses. The suture anchor and suture are not intended to provide indefinite biomechanical integrity.
7. Implantation of the all suture anchor requires preparation of the insertion site. Predrilling with the appropriate drill bit is the preferred method of site preparation.
8. Ensure the anchor placement is aligned with the drilled hole. Proper alignment is essential for successful repair.
9. Use of excessive force during insertion can cause failure of the suture anchor or insertion device
10. Bone quality must be adequate to allow proper placement of the suture anchor.
11. Do not alter the implant or instrumentation, otherwise performance may be compromised.
12. Once seated, do not rotate the suture anchor device in the bone as this may cause device failure.
13. Postoperative range of motion is to be determined by the physician.
14. After use, this device may be a potential biohazard and should be handled in accordance with accepted medical practice and applicable local and national requirements.

6. ADVERSE EFFECTS

Complications are those seen with any method of internal fixation. Adverse effects associated include;

1. Mild inflammatory reaction
2. Foreign body reaction
3. Infection, both deep and superficial
4. Allergic reaction

7. INSTRUCTIONS FOR USE

1. Position the SIRONIX® Universal guiding cannula (sleeve) on the prepared bone surface.
2. Create a pilot hole in the bone for the anchor by advancing the drill bit of respective size (1.5mm, 1.8 mm or 2.5 mm) through the sleeve until the stopper of drill bit (on proximal end) contacts the Universal guiding cannula's (sleeve's) handle. Safely remove the drill bit and ensure no movement of sleeve.
3. Open a sterile SIRONIX® STATIV® anchor and insert through the sleeve and into bone by gentle impaction using mallet until the anchor handle is flush with the back of the sleeve handle which indicates the anchor has been fully inserted below the cortex of bone.
4. Release the sutures/tapes from the anchor handle then remove the inserter by just pulling away from the anchor & also remove the SIRONIX® Universal guide cannula (sleeve)
5. The handle being removed, pull all the sutures/tapes upwards together to deploy/ bunch the SIRONIX® STATIV® all suture anchor with appropriate force. Apply even force without toggle effect to ensure complete deployment. [Forms unique Tri-leaflet bunch]
6. EXCESSIVE FORCE MAY OVERLOAD THE ANCHOR OR SUTURE/TAPE.
7. Use the sutures provided for soft tissue fixation.

8. WARRANTY

This product is warranted to be free from defects in material and workmanship.

Do not reuse.

9. STORAGE

Store in a cool dry place below 30 Degree Celsius (86 Degree Fahrenheit), away from moisture and direct heat. Discard if open but unused. Do not use after expiration date.

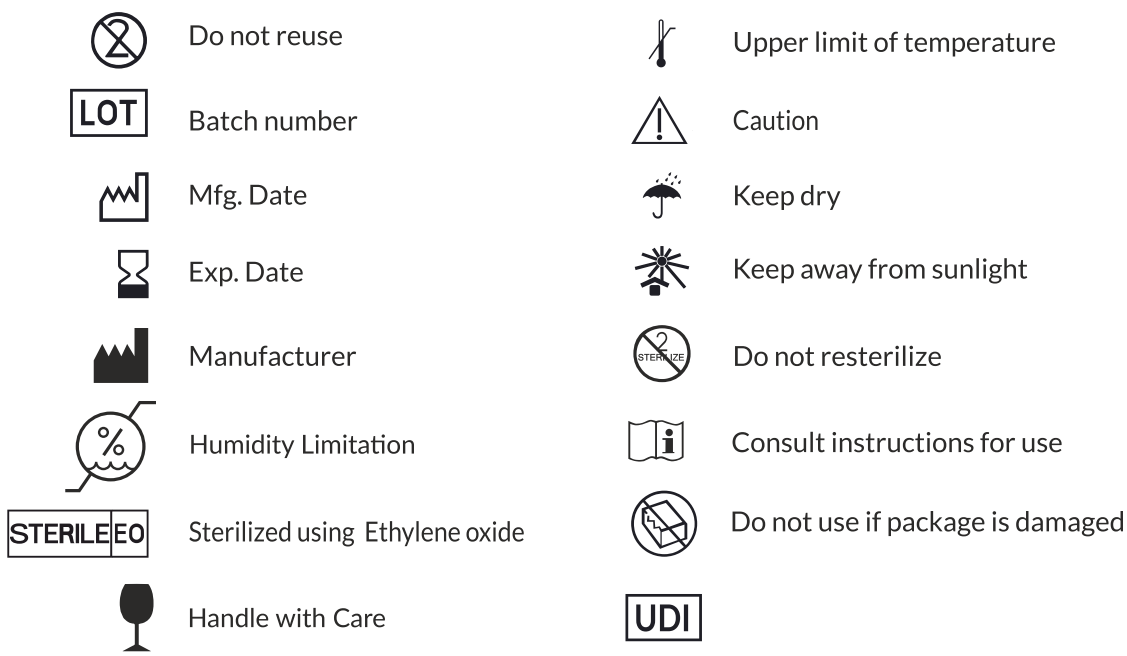
10. STERILIZATION

The SIRONIX® STATIV® All Suture Anchor is provided sterile. Do not resterilize.

11. FOR FURTHER INFORMATION

If further information on this product is needed, contact SIRONIX® Arthroscopy Solutions Customer Service or an authorized representative.

12. PACKING & LABELING



Shelf Life : 3 Years

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SIRONIX

Arthroscopy Solutions

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