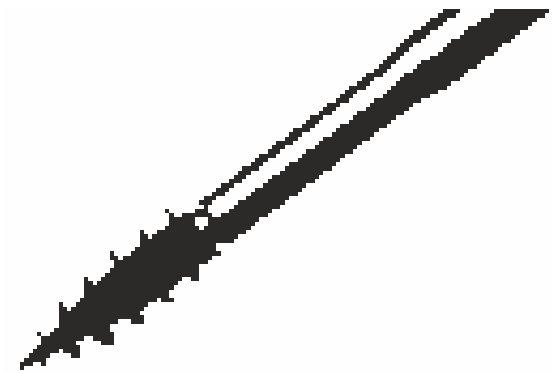
SIRONIX

Arthroscopy Solutions

CEPTRE®

Titanium Anchor

Product Instructions for Use (IFU) Booklet



CEPTRE® TITANIUM: IFU V03 | Date : 01/NOV/2021

CEPTRE® TITANIUM ANCHOR

1. DESCRIPTION

The SIRONIX®CEPTRE®Titanium Anchor is a threaded Metal knotted suture anchor preloaded on a disposable inserter assembly intended for fixation of two or three strands of #2 suture to bone. The implant is supplied sterile ready to use.

MATERIALS

Anchor: Titanium Alloy*(ASTMF136-13)*
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: Polycarbonate and polypropylene
Shaft of inserter: Stainless steel

2. INDICATIONS

The SIRONIX® CEPTRE® anchors are intended to be used for suture (soft tissue) fixation to bone 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. Procedures other than those listed in the INDICATIONS section.
2. Pathologic conditions of bone such as cystic changes or severe osteopenia that would impair its ability to securely fix the anchor
3. Pathologic changes in the soft tissues being fixated to bone that would prevent their secure fixation by the anchor.
4. Comminuted bone surface that would militate against secure fixation of the anchor.
5. Physical conditions that would eliminate or tend to eliminate adequate implant support or retard healing, i.e. blood supply limitation, previous infection, etc.
6. Conditions which tend to limit the patient's ability to restrict activities or follow directions during the healing period.
7. The anchor is not designed for and should never be used to attach artificial ligaments.
8. Known hypersensitivity to the implant material. Where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantation.
9. Any active infection or blood supply limitations.
10. The use of this device may not be suitable for patients with insufficient or immature bone. The physician should carefully assess bone quality before performing orthopedic surgery on patients who are skeletally immature. The use of this medical device and the placement of hardware or implants must not bridge, disturb or disturb o disrupt the growth plate.

4. WARNINGS

1. SIRONIX® anchors are designed to fix into cortical or cancellous bone. Bone stock must be adequate to allow proper and secure anchor placement. Incomplete insertion or poor bone quality may result in anchor pull out.
2. Immediate range of motion should be avoided to allow biological bony/soft tissue healing.

3. This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the thoracic or lumbar spine.
4. Users should be familiar with surgical procedures and techniques involving non-absorbable suture before employing suture for wound closure, as risk of wound dehiscence may vary with the site of application and the suture material used.
5. This product is for single-use only. It has not been designed to be re- used/re-sterilized. Reprocessing may lead to changes in material characteristics such as deformation and material degradation which may compromise device performance. Reprocessing of single use devices can also cause cross, contamination leading to patient infection. These risks may potentially affect patient safety.
6. 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.
7. Pre-operative and operating procedures, including knowledge of surgical techniques and proper selection and placement of the device, are important considerations in the successful utilization of this device. The appropriate delivery system is required for proper implantation of the device.
8. Only use recommended SIRONIX® Drill bits and drill guide.
9. Maintaining correct alignment throughout the drilling is required to ensure hole integrity.
10. 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.
11. Metal implants only: Devices that have been implanted for a long period of time may require the use of screw removal instrumentation.
12. Detailed instructions on the use and limitations of the device should be given to the patient.

13. Metal Implants Only : Removal of supplemental fixation after healing. If the supplemental fixation is not removed following the completion of its intended use, any of the following complications may occur.
    (1) Corrosion, with localized tissue reaction or pain:
    (2) Migration of implant position resulting in injury;
    (3) Risk of additional injury from postoperative trauma;
    (4) Bending, loosening, and/or breakage, which could make removal impractical or difficult;
    (5) Pain, discomfort, or abnormal sensations due to the presence of the device,
    (6) Possible increased risk of infection; and
    (7) Bone loss due to stress shielding. The surgeon should carefully weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid re-fracture.
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. The SIRONIX® anchor is supplied STERILE, and is intended for single use only. DO NOT RESTERILIZE. Do not use if sterile packaging appears to be damaged.
2. Discard if open but unused. Do not use after expiration date.
3. Inspect all instruments for damage before use. Do not attempt to repair.
4. A surgeon should not begin clinical use of the SIRONIX® anchor without reviewing the instructions for Use and practicing the procedure in a skills laboratory.
5. Inserting the awl less than the specified depth, axial misalignment or levering with the anchor upon insertion, may result in anchor fracture.
6. Difficulty tensioning sutures may occur as a result of sutures twisting around anchor, excessive suture slack around the anchor upon insertion, malleting the anchor into the bone past the laser line to the shoulder, and/or immobile Rotator Cuff.

7. Do not apply a bending force to the inserter. This can damage the anchor or inserter tip.
8. 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.
9. Careful attention must be paid to asepsis and avoidance of anatomical hazards.
10. 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.
11. Do not use sharp instruments to manage / control sutures.

6. ADVERSE EFFECTS

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

1. Mild inflammatory reaction
2. Foreign body reaction
3. Infection, both deep and superficial
4. Allergic reaction
5. Metal implants only: dislocation/subluxation

7. INSTRUCTIONS FOR USE

1. Open a sterile SIRONIX® CEPTRE® Titanium anchor and position it on the prepared bone surface and establish the proper alignment.
2. Mallet the handle until first pitch of anchor contacts the bone, then rotate the anchor handle in a clockwise direction to insert the anchor into the bone, rotate until the laser marking on the shaft of inserter is flush with the bone.
3. Release the sutures/tapes from the anchor handle then remove the inserter by just gently pulling away from the anchor & also remove the Universal guide cannula (sleeve)
4. Pull sutures/ tapes to test that anchor is securely fixed inside the bone.
5. EXCESSIVE FORCE MAY OVERLOAD THE ANCHOR OR SUTURE/TAPE.
6. 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.

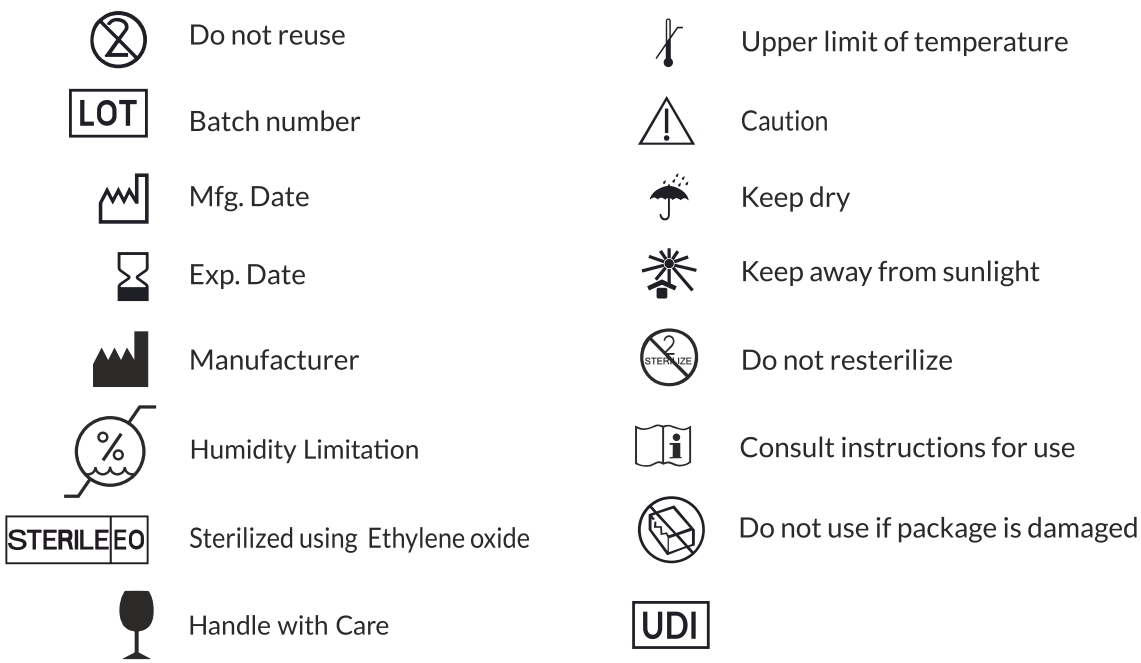
10. STERILIZATION

The SIRONIX® 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

CEPTRE® TITANIUM : IFU V03 | Date : 01/NOV/2021

SIRONIX

Arthroscopy Solutions

Manufactured and Marketed by:

Healthium

Healthium Medtech Ltd.
472-D, 13th Cross, 4th Phase, Peenya Industrial Area, Bangalore - 560058, India.
Customer Care No. : 080 - 41868198
Consumer Care Address : Same as Above
Email : care.sironix@healthiummedtech.com

Manufactured at :
Survey No. 388/1, Amsaran - Rohisa Road, Rohisa., Kheda, Gujarat (India) - 387110
Mfg. Lic. No. : MFG/MD/2021/000378