SIRONIX

Arthroscopy Solutions

CEPTRE®

PEEK / BTCP Anchors

Product Instructions for Use (IFU) Booklet

CEPTRE® PEEK / BTCP ANCHOR

1. DESCRIPTION

The SIRONIX®CEPTRE® PEEK (Polyether etherketone) / BTCP (β Tricalcium Phosphate) knotted anchor is available in Threaded & Tap in option made of knotted anchor preloaded on a disposable inserter assembly intended for fixation of suture / tape to bone. The implant is supplied sterile ready to use.

MATERIALS

Anchor: PEEK (Polyether ether ketone) / BTCP (β-Tricalcium Phosphate)
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 hyper sensitivity 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 medicals device and the placement of hardware or implants must not bridge or disturb the growth plate.

4. WARNINGS

1. SIRONIX® anchors are designed to hook 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 pullout.
2. Immediate range of motion should be avoided to allow biological bony/soft tissue healing.

3. This device is not approved screw attachment or fixation to the posterior element (pedicles) of the thoracic or lumbar spine.
4. Users should 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/resterilized. 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 safety.
6. Postoperatively and until healing is complete, fixation provided by this device should be considered as temporary and may not with stand 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 consideration 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. Detailed instruction on the use and limitation of the device should be given to the patient.
12. Patient sensitivity to the device materials should be considered prior to implantation. See adverse effects.
13. **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®PEEK / BTCP anchor is supplied STERILE, and is intended for single use only. DO NOT RESTERILIZE. Do not use if sterile packaging appears to bedamaged.
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. Asurgeon should not begin clinical use of the SIRONIX® anchor without reviewing the instructions for Use and practicing the procedure in skill 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.
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 requirement.
11. Do not use sharp instruments to manage/control sutures.

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

5. Allergic-like reactions to PLA materials (PLLA, PLDLA) have been reported. These reactions have sometimes necessitated the removal of the implant. Patient sensitivity to device materials must be considered prior to implantation.

7. INSTRUCTIONS FOR USE

1. Position the SIRONIX® respective awl (4.8mm or 5.5mm) on the prepared bone surface and establish the proper alignment.
2. Using a mallet, tap the awl into the bone until the first depth marking is flush with the bone surface, and then remove the awl.
3. Open a sterile SIRONIX® CEPTRE® PEEK / B-TCP anchor and position it at the mouth of the pilot hole and establish the proper alignment.
4. Rotate the 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.
5. Release the sutures/tapes from the anchor handle then remove the inserter by just pulling away from the anchor
6. Pull sutures/ tapes to test that anchor is securely fixed inside the bone.
7. EXCESSIVE FORCE MAY OVERLOAD THE ANCHOR OR SUTURE/TAPE.
8. 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


Do not reuse

Batch number


Mfg. Date


Exp. Date


Manufacturer


Humidity Limitation

Sterilized using Ethylene oxide


Handle with Care


Upper limit of temperature


Caution


Keep dry


Keep away from sunlight

Do not resterilize


Consult instructions for use


Do not use if package is damaged

Shelf Life : 3 Years

CEPTRE® PEEK/BTCP: 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