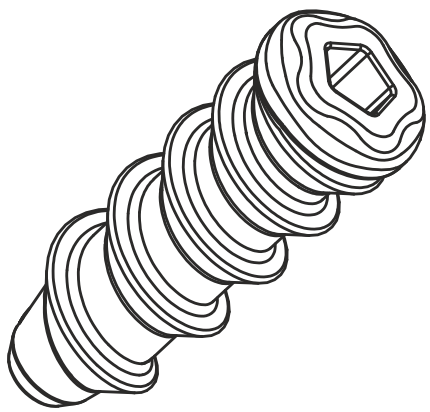
SIRONIX

Arthroscopy Solutions

HELYSIS®

Interference Screw

Product Instructions for Use (IFU) Booklet



HELYSIS®: IFU V03 | Date : 01/NOV/2021

HELYSIS® INTERFERENCE SCREW

1. DEVICE DESCRIPTION

The HELYSIS® Interference Screw family includes the screws in PLLA, PLLA-BTCP (β-Tricalcium Phosphate)composite material , Titanium alloy & PEEK (Polyether ether ketone).
These interference screw products are threaded and cannulated.

MATERIAL

The device is made of either PLLA (Poly -L-Lactide), PLLA and β-Tricalcium Phosphate composite or PEEK (Polyether ether ketone) or Titanium Alloy (ASTMF136-13) Refer to the package label for the material.

2. INDICATIONS

HELYSIS® Interference Screws are intended to be used for fixation of tissue, including ligament or tendon to bone, or a bone/tendon to bone. See below for specific indications.
Knee : Anterior Cruciate Ligament (ACL) Repair, Medical Collateral Ligament (MCL) Repair, Lateral Collateral Ligament (LCL) Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis, Posterior Cruciate Ligament (PCL) Repair.

3. CONTRAINDICATIONS

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. Foreign Body Reactions. See Adverse Effects-Allergic Type Reactions.
5. Any active infection or blood supply limitations.
6. Conditions that tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period.
7. 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.

8. Do not use for surgeries other than those indicated.

4. WARNINGS

1. An internal fixation device must never be reused.
2. Metal implants only : All metallic implant devices used for this surgical procedure should have the same metallurgic composition.
3. Bio absorbable implants: DO NOT RE-STERILIZE THIS DEVICE.
4. 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.
5. 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.
6. Only use recommended SIRONIX® Drill bits and drill guide along with SIRONIX® Jigs.
7. Maintaining jig alignment throughout the drilling is required to ensure tunnel integrity.
8. 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.
9. Metal implants only: Devices that have been implanted for a long period of time may require the use of screw removal instrumentation.
10. Detailed instructions on the use and limitations of the device should be given to the patient.
11. 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.
12. 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
(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.

13. Patient sensitivity to the device materials should be considered prior to implantation. See adverse effects.
14. **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. The use of surgical implants provides the orthopedic surgeon with a means of accurate fixation and helps generally in the management of fractures and reconstructive surgery. These implants are intended as aids to normal healing, but are not intended to replace normal body structures or bear the weight of the body in the presence of incomplete bone healing.
4. Ensure the endoscopic cannulated drill bit does not breach the femoral cortex, otherwise the femoral fixation with the fixation device will be compromised.
5. 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.

6. Careful attention must be paid to asepsis and avoidance of anatomical hazards.
7. 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.
8. Do not use sharp instruments to manage / control sutures.
9. Under insertion of the device may leave the proximal end of the implant protruding beyond the cortical bone, which could potentially cause soft tissue irritation and/or pain post-operatively.
10. Bio-Screw Interference Screw: Insert the screw driver into the screw to a fully seated position. Failure to engage the screw completely may result in damage to the implant.
11. Bio-absorbable Interference Screw only : It is important to completely seat the screwdriver to prevent potential stripping of the hex and/or screw fracture during insertion or removal.
12. Bio-absorbable interference Screw only: If inserting the Interference Screw through the anteromedial portal, appropriate knee flexion must be maintained throughout the entire insertion process. If achieving and maintaining the appropriate flexion angle is not possible or reasonable, a central trans-patellar tendon portal should be considered for proper insertion.
13. Bio-absorbable Interference screw only : During screw size changes or revision procedures, the sheath may be reinserted with the screwdriver over a guide pin to back out the screw in the sheath for arthroscopic removal.

6. ADVERSE EFFECTS

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

1. Infections, both deep and superficial
2. Foreign body reactions.
3. 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.

4. Metal implants only: dislocation/subluxation.
5. Mild inflammatory reaction

7. INSTRUCTIONS FOR USE

1. Using the SIRONIX® Tibial Jig drill the 2.3 mm passing pin through the tibia.
2. The soft tissue graft is prepared on the SIRONIX® Graft Preparation board.
3. The graft is pulled into place and fixed in the femoral tunnel using a preferred method.
4. With passing pin in place, ream the tibial tunnel as per the thickness of graft prepared (measured on graft sizing block)
5. Now, create further dilation of tunnel using SIRONIX® Screw Starter unit up to desired diameter. This will facilitate easier insertion of SIRONIX® HELYSIS® Interference Screw.
6. Place a 2mm diameter Guide wire in the tibial tunnel parallel to the graft bundle.
7. Load appropriately sized SIRONIX® HELYSIS® Interference screw onto the specified screw driver. The length of the screw must be equal to or less than the tibial tunnel length and the screw diameter must be no greater than 2mm larger than the tunnel diameter
8. Engage the guide wire with the SIRONIX® HELYSIS® Interference Screw and Driver assembly and advance to the insertion site.
9. While applying tension to the graft, insert the SIRONIX® HELYSIS® Interference Screw into the tibial tunnel, maintaining adequate axial force and turning the screw driver in clockwise direction.
10. If the screw is too tight do not push the screw, turn the screw half a turn reverse, allow 5 seconds for bone compression and then advance with clockwise rotation for fixation
11. Advance the screw until the proximal face is flush with the anterior cortical surface.
12. Ensure the SIRONIX® HELYSIS® Interference Screw is flush by palpating the proximal face of the Screw at the insertion site.
13. Disengage the Driver from the Screw and remove the guide wire.

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.

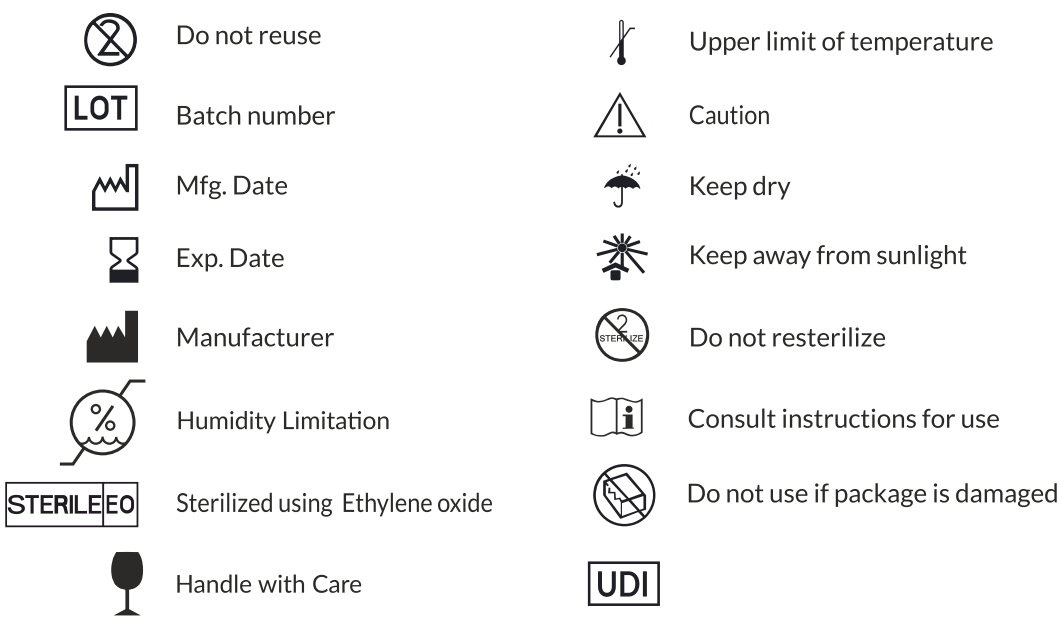
10. FOR FURTHER INFORMATION

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

11. STERILIZATION

The SIRONIX® HELYSIS® Interference Screw is provided sterile.
DO NOT RESTERILIZE.

12. PACKING & LABELING



Shelf Life : 3 Years

HELYSIS®: V03 | Date : 01/NOV/2021

SIRONIX

Arthroscopy Solutions

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