Titan
Interference and Mini Interference Screws
Instructions for Use

② STERILE EO

A. Device Description

The Titan Interference and Mini Interference Screws are interference screws for use in fixation of ligament, tendon, bone, or soft tissue to bone in knee, shoulder, foot/ankle, elbow, and hand/wrist procedures. The screws are provided sterile, for single use only.

Contents

- 1 ea. - Non-absorbable interference or Mini Interference screw made from ZENIVA™ ZA-500 PEEK (polyetheretherketone) from SOLVAY ADVANCED POLYMERS or Titanium 6AL-4V ELI. Refer to individual product label for specific material and diameter and length of screw.

B. Indications –Interference Screws

The Titan Interference Screws are indicated for the reattachment of ligament, tendon, soft tissue, or bone to bone during cruciate ligament reconstruction surgeries of the knee. All screws with a diameter of 9 mm or less and a length of 23 mm or less are also intended for the use in the following procedures:

Knee

- ACL repairs
- PCL repairs
- Extra-capsular repairs
    - Medial collateral ligament
    - Lateral collateral ligament
    - Posterior oblique ligament
- Patellar realignment and tendon repairs
    - Vastus medialis oliquous advancement
- Iliotibial band Mini Interference

Shoulder

- Capsular stabilization
    - Bankart repair
    - Anterior shoulder instability
    - SLAP lesion repairs
    - Capsular shift of capsulolabral reconstructions
- Acromioclavicular separation repairs
- Deltoid repairs
- Rotator cuff tear repairs
- Biceps Mini Interference

Foot and Ankle

- Hallux valgus repairs
- Medial or lateral instability repairs/reconstructions
- Achilles tendon repairs/reconstructions
- Midfoot reconstructions
- Metatarsal ligament/tendon repairs/reconstructions
- Bunionectomy
- Flexor Hullucis Longus
- Tendon transfers

Elbow, Wrist, and Hand

- Biceps tendon reattachment
- Ulnar or radial collateral ligament reconstructions
- Lateral epicondylitis repair
- Scapholunate ligament reconstruction
- Tendon transfers
- Carpomedicarpal joint arthroplasty
- Carpal ligament reconstruction

C. Indications –Mini Interference Screws

The Titan Mini 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.

The Mini Interference Screws are intended to provide soft tissue reattachment (i.e. fixation of ligament and tendon graft tissue).

See below for specific indications.

Shoulder

- Capsular stabilization
    - Bankart repair
    - Anterior shoulder instability
    - SLAP lesion repairs
    - Capsular shift of capsulolabral reconstructions
- Acromioclavicular separation repairs
- Deltoid repairs
- Rotator cuff tear repairs
- Biceps Mini Interference

Foot and Ankle

- Hallux valgus reconstruction
- Medial stabilization
- Lateral stabilization
- Achilles Tendon Repair
- Midfoot reconstructions
- Metatarsal ligament repair
- Bunionectomy
- Flexor Hullucis Longus for Achilles Tendon reconstruction
- Tendon transfers in the foot and ankle

Knee

- Medial Collateral Ligament Repair
- Lateral Collateral Ligament Repair
- Patellar Tendon Repair
- Posterior Oblique Ligament Repair
- Illiotibial Band Mini Interference
- Posterior Cruciate Ligament Repair

Elbow

- Biceps tendon reattachment
- Ulnar or radial collateral ligament reconstruction

Wrist and Hand

- Scapholunate Ligament Reconstruction
- Ulnar Collateral Ligament Reconstruction
- Radial Collateral Ligament Reconstruction
- Carpometalcarpal joint arthroplasty (basal thumb joint arthroplasty)
- Carpal Ligament Reconstructions and repairs
- Tendon transfer in the hand/wrist
- Lateral Epicondylitis repair

D. Contraindications

- Screws that are smaller than 7mm may not be appropriate for the knee indication.
- Insufficient quantity or quality of bone.
- Blood supply limitations and previous infections which may retard healing.
- Foreign-body sensitivity. Where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantation.
- Foreign Body Reactions. See Adverse Effects-Allergic Type Reactions.
- Any active infection or blood supply limitations.
- Conditions that tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period.
- 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 disrupt the growth plate.
- Do not use for surgeries other than those indicated.

E. Adverse Effects

- Infections, both deep and superficial.
- Foreign body reactions.
- Adverse reactions to implant materials have sometimes necessitated the removal of the implant. Patient sensitivity to device materials must be considered prior to implantation.
- **Metal implants only:** Shoulder dislocation/subluxation.

F. Warnings

- **Note:** Surgeons must apply their professional judgment when determining the appropriate screw size based on the specific indication, preferred surgical technique, and patient history.
- An internal fixation device must never be reused.

- **Metal implants only:** All metallic implant devices used for this surgical procedure should have the same metallurgical composition.
- Postoperatively and until healing is complete, fixation provided by this device should be considered as temporary and may not withstand weigh 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.
- 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.
- 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.
- Detailed instructions on the use and limitations of the device should be given to the patient.
- 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.
- This device has not been evaluated for safety and compatibility in the magnetic resonance (MR) environment. This device has not been tested for heating or migration in the MR environment. If the implant is manufactured from a metallic material, surgeons can expect that MR artifacts will be present during routine MR imaging.
- **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 the benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid re-fracture.
- Patient sensitivity to the device materials should be considered prior to implantation. See Adverse Effects.

G. Precautions

U.S. Federal law restricts this device to sale by or on the order of a physician.

- Surgeons are advised to review the product-specific surgical technique prior to performing any surgery. Detailed surgical techniques in print and electronic formats are available. Or, contact your representative for an onsite demonstration.
- 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.
- Prior to use, inspect the device to ensure it is not damaged. Do not use a damaged device.
- Excessive force should not be placed on the delivery instrument.
- Careful attention should be paid to asepsis and avoidance of anatomical hazards.
- 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.

H. Packaging and Labeling

- Implant devices should be accepted if the factory packaging and labeling arrive intact.
- Contact Customer Service if package has been opened or altered.

I. Material Specifications

Refer to the packaging label for the implant materials.

The device is made of titanium or polyetheretherketone (PEEK).

J. Sterilization (Instruments)

The instruments for the Titan Interference Screws are delivered non-sterile, disassembled, and should be disassembled and sterilized in accordance with the following steam and dry time specifications:

Cycle Type	Cycle Time	Temperature	Packaging	Dry time
Pre-vacuum	4 minutes	132° C	Double Autoclave Wrap	20 minutes

K. Storage Conditions

All devices must be stored in the original unopened packaging, away from moisture and should not be used after the expiration date.

L. Information

Surgeons are advised to review the product specific surgical technique prior to performing any surgery. Detailed surgical techniques are available in print and electronic formats. Or, contact your authorized representative for an onsite demonstration.

If further information is needed, contact ABC Acromion Customer Service or your authorized representative.

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