ENGLISH

A. DEVICE DESCRIPTION

InterF-ix is a titanium button specially designed for ligamentoplasty surgical techniques including anterior/posterior cruciate ligament reconstructions, reinsertion of the long-head of the biceps tendon and ankle ligaments. InterF-ix Buttons come in Certified ISO 5832-3 Medical Grade Titanium (Ti 6AI 4V).

B. INDICATIONS

The Ortho-Design InterF-ix Buttons are intended for the fixation of bone to bone or soft tissue to bone, and are intended as fixation posts, a distribution bridge, or for distributing suture tension over areas of ligament or tendon repair.

- **Foot/Ankle:** Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Mid-foot Reconstruction Metatarsal Tendon Repair and Digital tendon transfers
- **Elbow:** Biceps Tendon Reattachment, Ulnar/Radial Collateral Ligament Reconstruction, and Lateral Epicondylitis repair
- **Knee:** Anterior Cruciate Ligament Repair, Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Iliotibial Band Tenodesis, Posterior Cruciate Ligament Repair, and Iliotibial Band Tenodesis, Quadriceps Tendon Repair.

C. 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. Any active infection or blood supply limitations.
5. Conditions that tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period.
6. 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 skeletally immature patients. The use of this medical device and the placement of hardware or implants must not bridge, disturb or disrupt the growth plate.
7. Do not use for surgeries other than those indicated.

D. ADVERSE EFFECTS

1. Foreign body reactions.
2. Allergies and other reactions to device materials.
3. Infections (Both deep and superficial)

E. WARNINGS

1. Caution: Federal law restricts this device to sale by or on the order of a physician.
2. This device is intended to be used by a trained medical professional.
3. An internal fixation device must never be re-used.
4. Do not re-sterilize this device.
5. 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.
6. 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 Ortho-Design delivery system is required for the proper implantation of the device.
7. 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.
8. Detailed instructions on the use and limitations of this device and the brochure (www.ortho-design.com/recources) should be given to the patient. Your surgeon will guide you in deciding what particular treatment is best for you and explain the benefits, risks, and contraindications associated with the treatment.
9. 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.
10. **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.
11. Biohazard waste, such as explanted devices, needles, and contaminated surgical equipment, should be safely disposed of in accordance with the institutions' policy.
12. Serious incidents should be reported to Ortho-Design (Pty) Ltd, or an in-country representative, and to the health authority where the incident occurred.

F. MRI SAFETY INFORMATION

Non-clinical testing and in-vivo electromagnetic simulations demonstrated that the InterF-ix Titanium Buttons are MR Conditional. A patient with this device can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 1.5-Tesla and 3-Tesla, only
- Maximum spatial gradient magnetic field of 3000 Gauss/cm or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 1-W/kg for 15 minutes of scanning in the Normal Operating Mode of operation for the MR system

G. PRECAUTIONS

1. Surgeons must apply their professional judgment when determining the appropriate InterF-ix Button size based on the specific indication, preferred surgical technique, and patient history.
2. Surgeons are advised to review the product-specific surgical technique prior to performing any surgery. Ortho-Design provides detailed surgical techniques in print and electronic formats. The Ortho-Design website also provides detailed surgical technique information and demonstrations. Alternatively, contact your Ortho-Design representative for an on-site demonstration.

H. PACKAGING AND LABELING

1. Ortho-Design devices should be accepted only if the factory packaging and labelling arrive intact.
2. Contact Customer Service if the package has been opened or altered.
3. All of the symbols used on the labelling along with the title, description, and standard designation number may be found on our website at www.ortho-design.com

I. STERILIZATION

This device is provided sterile. Check the package labelling for more information. This device should never be re-sterilized under any conditions. Certain Ortho-Design instruments that may be used during this procedure are provided non-sterile and must be adequately cleaned and sterilized prior to use or re-use. Please refer to DFU-0023-XX and ANSI/AAMI ST79 for specific information.

J. MATERIAL SPECIFICATIONS

Refer to the package label for the materials. InterF-ix Titanium Buttons are manufactured from Certified ISO 5832-3 Medical Grade Titanium (Ti 6AI 4V).

K. STORAGE CONDITIONS

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

L. INFORMATION

- Procedures carried out using these devices may be used on the general population.
- Clinical benefits associated with the use of these devices outweigh the known clinical risks.
- There are no unacceptable residual risks or uncertainties associated with the clinical use of these devices.

ORTHO-DESIGN

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