ENGLISH

A. DEVICE DESCRIPTION

The Ortho-Design VersaPEEK™ suture anchors consist of an internal eyelet connected with two, or three USP 2 UHMWPE non-absorbable sutures. The VersaPEEK™ is a screw-in anchor made from medical grade PEEK.

B. INDICATIONS

The VersaPEEK™ Suture Anchor is intended to be used for soft tissue fixation during general orthopedic surgery. The VersaPEEK™ Suture Anchor is intended for use in arthroscopic or open surgical approaches for fixation of soft tissue and ligaments to bone/healthy tissue during tendon and ligament repairs, during procedures such as:

- Shoulder: Rotator cuff repair, biceps tenodesis, SLAP repair, Bankart repair
- Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus
- Elbow: Tennis elbow repair
- Knee: Medial and lateral collateral ligament repair.
- Wrist: Scapholunate ligament reconstruction

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

D. ADVERSE EFFECTS

1. Foreign body reactions.
2. Shoulder dislocation/subluxation
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. All metallic implant devices used for this surgical procedure should have the same metallurgical composition.
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 Ortho-Design delivery system is required for the proper implantation of the device.
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. 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.
10. 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.
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

MR Conditional

The VersaPEEK™ has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the VersaPEEK™ in the MR environment is unknown. Scanning a patient who has this medical device may result in patient injury.

G. PRECAUTIONS

1. Surgeons must apply their professional judgment when determining the appropriate suture anchor 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.
3. Make sure to use a drill bit and the designated tap to create the bone socket.
4. During anchor insertion, ensure that the angle of anchor insertion is coaxial to that of the previously prepared bone socket.
5. Ensure that the anchor body is in full contact with the bone before advancing the anchor body into the prepared bone socket.

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 labeling 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. These devices consist of either one component. The component is manufactured from polyetheretherketone (PEEK). **Suture:** See package label for size and type of suture provided with the device. The sutures supplied meet or exceed U.S. and European Pharmacopeia standards for non-absorbable surgical sutures (except for diameter requirements).

K. STORAGE CONDITIONS

Non-bioabsorbable 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.

VersaPEEK™
Suture Anchors:
VersaPEEK 4.5 x 15mm
VersaPEEK 5.5 x 15mm

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Rev 01

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