ENGLISH

A. DEVICE DESCRIPTION

The Ortho-Design VersaLat™ 4.75mm, 5.5mm, 6.5mm, and 7.5mm knotless anchors consist of a cannulated body with one #2 Force Fiber non-absorbable retention suture passing through. The VersaLat™ is a knotless anchor made from medical grade PEEK, with a Titanium MR-indicating button at the tip. The VersaLat™ 4.75mm has a titanium alternative.

B. INDICATIONS

The Ortho-Design 4.75mm VersaLat Knotless Anchor is intended for soft tissue fixation to bone in the foot, ankle, hand, and elbow.

- **Foot/Ankle:** Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Mid-foot Reconstruction, Hallux Valgus Reconstruction Metatarsal Ligament Repair Metatarsal Tendon Repair and Digital tendon transfers Elbow: Biceps Tendon Reattachment, Ulnar/Radial Collateral Ligament Reconstruction, and Lateral Epicondylitis repair.
- **Hand/Wrist:** Scapholunate Ligament Reconstruction and Ulnar/Radial Collateral Ligament Reconstruction. Digital Tendon Transfers. Carpometacarpal Joint Arthroplasty
- **Knee:** Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, and Iliotibial Band Tenodesis, Quadriceps Tendon Repair.

The VersaLat™ 5.5mm, 6.5mm, 7.5mm Knotless Anchors are intended to use 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
- **Elbow:** Biceps Tendon Reattachment, Ulnar/Radial Collateral Ligament Reconstruction.
- **Knee:** Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, and Iliotibial Band Tenodesis

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. Shoulder dislocation/subluxation
3. Infections (Both deep and superficial)

E. WARNINGS

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 or punch to create the bone socket.
4. Make sure to use a tap/drill for both the 6mm and 7mm VersaLat. This is essential due to the difference in size and indication purposes.
5. During anchor insertion, ensure that the angle of anchor insertion is coaxial to that of the previously prepared bone socket.
6. Ensure that the anchor body is in full contact with the bone before advancing the anchor body into the prepared bone socket.
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. Biohazard waste, such as explanted devices, needles, and contaminated surgical equipment, should be safely disposed of in accordance with the institutions' policy.
11. 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

Not evaluated.

MR Safe

Not evaluated.

G. PRECAUTIONS

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.

H. PACKAGING AND LABELING

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

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 or two components. Each component is manufactured from either titanium alloy or polyetheretherketone (PEEK) or both.
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.

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