ENGLISH

A. DEVICE DESCRIPTION

The SoftLock™ All Suture Anchor is a fixation device intended to provide secure fixation of soft tissue to bone. It consists of soft tissue anchor with non-absorbable suture(s) to an inserter with a handle. The anchors are available in various sizes, preloaded with suture and/or tape combinations. This device is provided sterile, for single use only.

MATERIAL
Anchor: Non-absorbable suture anchor, braided, UHMWPE
Suture: Braided, ultra-high molecular weight polyethylene (UHMWPE) #2 suture
Tape: Braided, Ultra high molecular weight polyethylene (UHMWPE) 1.5mm flat tape
Handle: ABS Plastic
Shaft of inserter: Stainless Steel

B. INDICATIONS

The SoftLock™ All Suture anchor are intended for use for suture or soft tissue fixation in the foot, ankle, knee, elbow, hand wrist, and hip for the following indications:

1. **Shoulder:** Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Capsular Shift and Capsulolabral Reconstruction
2. **Foot/Ankle:** Achilles Tendon Repair, Lateral Stabilization, Medial Stabilization, Mid-foot Reconstruction, and Digital tendon transfers
3. **Knee:** Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, and Iliotibial Band Tenodesis, secondary or adjunct fixation for ACL/PCL reconstruction or repair, and joint capsule closure.
4. **Hand/Wrist:** Scapholunate Ligament Reconstruction. Digital Tendon Transfers with Carpometacarpal Joint Arthroplasty
5. **Elbow:** Biceps Tendon Reattachment, Ulnar/Radial Collateral Ligament Reconstruction, and Lateral Epicondylitis repair
6. **Hip:** Acetabular labral repair, Capsular repair.

C. ADVERSE EFFECTS

Complications are those seen with any method of internal fixation. Adverse effect associated include:

1. Mild inflammatory reaction
2. Foreign body reaction
3. Infection, both deep and superficial
4. Allergic reaction

D. CONTRAINDICATIONS

1. Procedures other than those listed in the INDICATIONS sec on.
2. Known active infections.
3. Pathological conditions in the soft tissue that would prevent secure fixation of the implant.
4. Known hypersensitivity to the implant material. Where material sensitivity is suspected, appropriate tests should be made, and sensitivity ruled out prior to implants on.
5. Physical conditions that would eliminate or tend to eliminate adequate implant support or retard healing, i.e., blood supply limitation, previous infection on, etc.
6. Conditions which tend to limit the parent's ability to restrict ac vi es or follow directions during the healing period.
7. The anchor is not designed and should never be used to attach artificial ligaments.
8. Comminuted bone surface, which would compromise secure anchor fixation.

E. WARNINGS

1. Do not use if package is damaged. Do not use if the product sterilization barrier or its packaging is compromised.
2. Contents are sterile unless package is opened or damaged. DO NOT RESTERILIZE. For single use only.
   Discard any open, unused product. Do not use after the expiration date.
3. It is the surgeon's responsibility to be familiar with the appropriate surgical techniques prior to use of this product.
4. Read these instructions completely prior to use.
5. Maintaining guide alignment through drilling is required to ensure drill hole integrity
6. Do not attempt to implant this device with cartilage epiphyseal growth plates of non- osseous tissue.
7. Do not resterilize or reuse anchors, sutures and insertion devices packaged with the anchor.
8. Incomplete anchor insertion may result in poor anchor performance.
9. Breakage of suture anchor can occur if insertion site is not properly prepared with appropriate instrumentation.
10. Postoperatively and until healing is complete, fixation provided by this device should be considered as temporary and may not withstand weightbearing or this device should be protected. The postoperative regime prescribed by the physician should be strictly followed to avoid adverse stresses applied to the device.
11. 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
12. Detailed instructions on the use and limitations of the device should be given to the patient
13. This is a single us device. Reuse of this device could result in a failure of the device top perform as intended and could cause harm to the patient and/or user
14. Patient sensitivity to the device materials should be considered prior to implementation. See adverse effects.

F. MRI SAFETY INFORMATION

MR Safe

The SoftLock anchor body is manufactured from only UHMWPE and polyester with or without silicone elastomer coating, cyanoacrylate, and nylon are MR safe.

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 a on-site demonstration.
3. Make sure to use the recommended accessories with the product.
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 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. These devices consist of either one or two components. Each component is manufactured from UHMPWE

Suture: See package label for size and type of suture provided with 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

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.

L. INFORMATION

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

M. INSTRUCTIONS FOR USE

1. Position the guiding cannula (sleeve) on the prepared bone surface.
2. Create a pilot hole in the bone for the anchor by advancing the drill bit of respective size (1.5mm, 1.8mm, 2.5mm or 2.9mm) through the sleeve until the stopper of the drill bit (on proximal end) contacts the universal guiding cannula's (sleeve's) handle. Safely remove the drill bit and ensure no movement of sleeve.
3. Open a sterile STATIV anchor and insert through the sleeve and into bone by gentle impaction using mullet until the anchor handle is flush with the back of the sleeve handle which indicates the anchor has been fully inserted below the cortex of bone.
4. Release the sutures/tapes from the anchor handle then remove the inserter by just pulling away from the anchor & also remove the universal guide cannula (sleeve).
5. The handle being removed, pull all the sutures/tapes upwards together to deploy/bunch the STATIV all suture anchor with appropriate force. Apply even force without toggle effect to ensure complete deployment.
6. EXCESSIVE FORCE MAY OVERLOAD THE ANCHOR OR SUTURE/ TAPE.
7. Use the sutures provided for soft tissue fixation.

SoftLock™
All Suture Anchor:
1.5mm, 1.8mm, 2.5mm, 2.9mm

Doc no: ORTHO-04-13-02
Rev 02

ORTHO-DESIGN
ORTHOPAEDIC INNOVATION

Ortho-Design (PTY) Ltd. Operates from:
Floor 2
17 Dely Road
Hazelwood
Pretoria
South Africa
Tel: (+27) 12 807 5172
www.ortho-design.com

EC REP
TNMC Device Limited
Krezmina 1,
10000
Zagreb
Croatia
Tel: +(38) 591 622 9658
tnmchr@tnmc.biz
www.tnmc.biz