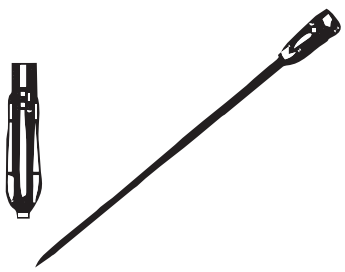
SIRONIX

ArthroscopySolutions

STATIV®

Knotted UHMWPE Suture Anchor

PRODUCT INSTRUCTIONS FOR USE (IFU) BOOKLET



PRODUCT DESCRIPTION:

The Knotted UHMWPE suture anchor is a fixation device intended to provide secure fixation of soft tissue to bone and is available in self-tap/self-punching variant also. It consists of a soft suture anchor with attached non-absorbable suture(s) to an inserter with handle. The anchors are available in various sizes, preloaded with suture, tape or suture–tape combinations. This device is provided sterile, for single use only.

MATERIALS SPECIFICATIONS:

Anchor
- **Loop** : Non-absorbable, UHMWPE USP#3/USP#7 (UHMWPE ≥ 97.50%)
- **Suture** : Non-absorbable, UHMWPE USP #2 (UHMWPE ≥ 99.45% & Black Colour ≤ 0.55%)
- **Tape** : Non-absorbable UHMWPE 1.5mm available in Flat & Round-Flat-Round (UHMWPE ≥ 99.45% & Black Colour ≤ 0.55%)
- **Additive** : Polycaprolactone (≤2.50% in the Loop)

Dispenser : Stainless steel (SS 300 Series)
Handle : ABS (Acrylonitrile Butadiene Styrene)
Ring : Silicone rubber ring

VARIANTS:

- Knotted UHMWPE Suture Anchor-1.5mm
  Single loaded suture-USP #2
- Knotted UHMWPE Suture Anchor-1.5mm
  Single loaded tape-1.5mm
- Knotted UHMWPE Suture Anchor-1.8mm
  Single loaded suture-USP #2
- Knotted UHMWPE Suture Anchor-1.8mm
  Single loaded tape-1.5mm
- Knotted UHMWPE Suture Anchor-1.8mm
  Double loaded sutures-USP #2
- Knotted UHMWPE Suture Anchor-1.8mm
  Double loaded tapes-1.5mm
- Knotted UHMWPE Suture Anchor-2.5mm
  Double loaded sutures-USP #2
- Knotted UHMWPE Suture Anchor-2.5mm
  Double loaded tapes-1.5mm
- Knotted UHMWPE Suture Anchor-2.5mm
  Triple loaded sutures-USP #2
- Knotted UHMWPE Suture Self Tap Anchor-2.5mm
  Double loaded sutures-USP #2
- Knotted UHMWPE Suture Self Tap Anchor-2.5mm
  Triple loaded sutures-USP #2
- Knotted UHMWPE Suture Self Tap Anchor-2.5mm
  Double loaded tapes-1.5mm
- Knotted UHMWPE Suture Self Tap Anchor-2.9mm
  Double loaded sutures-USP #2
- Knotted UHMWPE Suture Self Tap Anchor-2.9mm
  Triple loaded sutures-USP #2
- Knotted UHMWPE Suture Self Tap Anchor-2.9mm
  Double loaded tapes-1.5mm

INTENDED PURPOSE:

The Knotted UHMWPE suture anchor with the sutures/tapes are Intended for soft tissue fixation to the bone.

INDICATIONS:

The Knotted UHMWPE suture anchor is indicated for:

1. **Shoulder:** Rotator cuff rupture, Bankart lesion, SLAP lesion, Biceps tenodesis, Capsular shift, and capsulolabral rupture.

2. **Elbow:** Biceps tendon rupture.
3. **Foot/Ankle:** Lateral stabilization, Medial stabilization, Achilles tendon rupture, and Mid-foot rupture.
4. **Hip:** Acetabular labral rupture.

CONTRAINDICATIONS:

1. Insufficient quantity or quality of bone.
2. Pathologic conditions of bone such as cystic changes or severe osteopenia that would impair its ability to securely fix the anchor.
3. Pathological conditions in the soft tissue that would prevent secure fixation of the implant.
4. Blood supply limitations and previous infections, which may retard healing.
5. Conditions that tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period.
6. The anchor is not designed for and shall never be used to attach artificial ligaments.
7. Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests shall be made, and sensitivity ruled out prior to implantation.

INTENDED USERS:

By trained and registered health care professional, trained in orthopaedic surgical procedures.

INTENDED PATIENT POPULATION:

This implant can be used in patients who are skeletally mature as per the treating physician, in line with the intended purpose, indications and contraindications.

PERFORMANCE:

UHMWPE suture being braided enables secured knots. It elicits a minimal initial inflammatory reaction in tissues which is followed by gradual encapsulation of the suture by fibrous connective tissue. UHMWPE suture is not absorbed, nor is it subjected to degradation or weakening by the action of tissue enzymes.

INSTRUCTIONS FOR USE:

1. Position the Universal 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, 1.8 mm or 2.5 mm) through the sleeve until the stopper of 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 Knotted UHMWPE suture anchor and insert through the sleeve and into bone by gentle impaction using mallet 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 Knotted UHMWPE suture anchor with appropriate force. Apply even force without toggle effect to ensure complete deployment. [Forms unique Tri-leaflet bunch]
6. Excessive force may overload the anchor or suture/tape.
7. Use the sutures provided for soft tissue fixation.

For Self-Tap Knotted UHMWPE suture anchor:

1. Identify the correct anatomical site for the insertion of the Knotted UHMWPE suture anchor.
2. Open the sterile Knotted UHMWPE suture anchor with the self-tap.
3. Mallet the proximal end of the anchor shaft until the most distal laser line crosses the cortical layer.
4. Release the sutures/tapes from the anchor handle then remove the inserter by just pulling away from the anchor.

5. Pull all the sutures/tapes upwards together to deploy/ bunch the Knotted UHMWPE suture anchor with appropriate force. Apply even force without toggle effect to ensure complete deployment. [Forms unique Tri-leaflet bunch]
6. Excessive force may overload the anchor or suture/tape.
7. Use the sutures provided for soft tissue fixation.

EXPLANTATION:

Knotted UHMWPE suture anchor is buried deep into the bone. In case of infection/s or loosening the Knotted UHMWPE suture anchor is removed by pulling the anchor away from the insertion point.

APPLICATIONS:

The implant shall be selected and implanted depending on patient's condition and surgical technique.

CLINICAL BENEFITS:

1. Arthroscopic glenoid labral lesion repair for the treatment of recurrent traumatic anterior shoulder instability with Knotted UHMWPE Suture Anchor yields excellent shoulder stability, motion, and function as shown by the improvement in ROWE scores from 35 ± 7.2 preoperatively, which increased to 93.6 ± 5.3 postoperatively at the mean follow-up of 28.8 months (range, 24-48 months) (P < .001).
2. Arthroscopic glenoid labral lesion repair for the treatment of recurrent traumatic anterior shoulder instability with Knotted UHMWPE Suture Anchor yields excellent functional recovery as shown by the improvement in Constant Murley Score from 65 ± 6.3 preoperatively, which increased to 92 ± 4.3 postoperatively at the mean follow-up of 28.8 months (range, 24-48 months) (P < .001).
3. Knotted UHMWPE Suture Anchor in arthroscopic Bankart repair yields comparative shoulder stability, motion, and function as shown by the improvement in ROWE scores at the end of a two-year follow-up period when compared to conventional biodegradable suture anchors (preoperatively, 41.4 ± 10.5 vs 41.3 ± 9.4; 2 years postoperatively, 87.9 ± 14.9 vs 88.5 ± 14.6; P = .857) respectively.
4. Knotted UHMWPE Suture Anchor fixation requires smaller bone sockets for placement. These anchors can be placed using a 1.4 mm to 1.8 mm bone tunnel, whereas hard body anchors may require a 2.4 mm to 3.0 mm tunnel. This is beneficial by allowing the placement of more anchors, increasing fixation points, and minimizing the risk of recurrence.
5. Knotted UHMWPE Suture Anchor fixation can be placed through curved guides, facilitating placement through standard anterior portals, and reducing the risk of glenoid perforation when compared with metallic anchors.
6. Knotted UHMWPE Suture Anchor are advantageous due to their bone preserving ability. They show a significantly narrower cortical defect as well as a smaller bone cavity following pullout (4.3 ± 1.3 mm vs. 5.3 ± 0.9 mm, p = 0.037; 141 mm^3 vs. 212 mm^3; p = 0.009) when compared to conventional PEEK suture anchors.
7. Anchor is loaded on minimalistic designed inserter device to give assured centralized deployment of the anchor into pilot hole and in difficult areas during labral repair. It also allows multiple anchor placement in glenoid rim.
8. The deployed unique tripod bunched up pattern doubles its size compared up to the original size of anchor and hence gives much higher pull-out strength.
9. Knotted UHMWPE Suture Anchor improve outcomes by offering bone preservation (decreased bone loss) & maintaining glenoid bone stock, greater surface contact area between bone and tendon, and more space for point of fixation when repairing massive tears.

LIMITATIONS:

1. It may result in tunnel expansion and cyst formation. During rotator cuff repairs, a small percentage of patients may develop fluid collection around the anchor with less than twice diameter of the anchor (grade 3 changes) but this does not appear to adversely influence clinical outcomes nor tendon healing rates.

WARNINGS:

1. It is the surgeon's responsibility to be familiar with the appropriate surgical techniques prior to use of this device.
2. Read these instructions completely prior to use.

3. Only use the recommended drill bits and drill guides intended for use with the Knotted UHMWPE suture anchor. Improper use of the instruments may injure the patient, damage the instruments, or compromise fixation.
4. Maintaining guide alignment throughout drilling is required to ensure drill hole integrity.
5. Do not attempt to implant this device within cartilage epiphyseal growth plates of non-osseous tissue.
6. Incomplete anchor insertion may result in poor anchor performance.
7. Breakage of the suture anchor can occur if the insertion site is not prepared with appropriate instrumentation prior to implantation.
8. Postoperatively and until healing is complete, fixation provided by this device shall be considered as temporary and may not withstand weight bearing or this device shall be protected. The postoperative regimen prescribed by the physician shall be strictly followed to avoid adverse stresses applied to the device.
9. Any decision to remove the device shall take into consideration the potential risk to the patient of a second surgical procedure. Device removal shall be followed by adequate postoperative management.
10. Detailed instructions on the use and limitations of the device shall be given to the patient.
11. Patient sensitivity to the device materials shall be considered prior to Implantation. See side effects.
12. This product is for single-use only. It has not been designed to be re-used/re-sterilized. Reprocessing may lead to changes in material characteristics such as deformation and material degradation which may compromise device performance. Reprocessing of single-use devices can also cause cross-contamination leading to patient infection safety.
13. 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.

PRECAUTIONS:

1. Hazards associated with reuse of this device include, but are not limited to, patient infection and/or device malfunction.
2. Prior to use, inspect the device to ensure it is not damaged. Do not use a damaged device.
3. Patient shall be instructed on the limitations of the implant and shall be cautioned regarding weight bearing and body stresses on the appliance prior to secure bone healing. Immobilisation required shall be as per the type and degree of injury, and as per the institutional protocol and respective national guidelines. The post-operative rehabilitation shall be advised as per the type and degree of injury, type of repair performed, and as per the institutional protocol and respective national guidelines.
4. Regulations restricts this device to sale by or on the order of a physician.
5. Do not use sharp instruments to manage or control the suture.
6. As with any suture anchor or suturing technique, the fixation given shall be considered as only temporary, until biological attachment of tissue to bone is completed, and may not withstand weight bearing or other unsupported stresses. The suture anchor and suture are not intended to provide indefinite biomechanical integrity.
7. Implantation of the Knotted UHMWPE suture anchor requires preparation of the insertion site. Predrilling with the appropriate drill bit is the preferred method of site preparation.
8. Ensure the anchor placement is aligned with the drilled hole. Proper alignment is essential for successful repair.
9. Use of excessive force during insertion can cause failure of the suture anchor or insertion device.
10. Bone quality must be adequate to allow proper placement of the suture anchor.
11. Do not alter the implant or instrumentation, otherwise performance may be compromised.
12. Once seated, do not rotate the suture anchor device in the bone as this may cause device failure.
13. Postoperative range of motion is to be determined by the physician.
14. The use of this device may not be suitable for patients with insufficient or immature bone. The physician shall carefully assess bone quality before performing orthopaedic 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.

SIDE EFFECTS:

1. Mild inflammatory reaction and foreign body reaction.
2. Infection, both deep and superficial.
3. Allergies and other reactions to device materials. These reactions have sometimes necessitated the removal of the implant. Patient sensitivity to devices materials must be considered prior to implantation.
4. Migration/expulsion of the device.
5. Device breakage, and tissue injury during application.

USE ENVIRONMENT:

Intended to be used in Operation theatre / Healthcare set up.

STERILIZATION:

The device is sterilized by Ethylene Oxide gas and is intended for single use only. Do not re-sterilize, do not reuse. Do not use if package is opened or damaged.

STORAGE:

Store in a cool dry place below 30 Degree Celsius (86 Degree Fahrenheit), away from moisture and direct heat. Do not use after expiry date.

SHELF LIFE:

5 years from the manufacturing date.

MRI SAFETY INFORMATION:

The Knotted UHMWPE suture anchor device made from non-absorbable UHMWPE braided sutures/tapes are MR safe.

DISPOSAL:

Discard used device in the container meant for bio-hazard/infectious waste. Unused expired pouches shall be incinerated or disposal shall be done as per local regulations.

SYMBOLS:

	Manufacturer	QTY	Quantity
	Mfg. Date & Country of manufacture		Keep away from sunlight
	Use-by date		Keep dry
LOT	Batch code	30° C	Upper limit of temperature
REF	Catalogue number		Do not re-use
STERILE EO	Sterilized using Ethylene oxide		Consult instructions for use
	Do not resterilize		Caution
	Do not use if package is damaged	MD	Medical Device
	Single sterile barrier system with protective packaging inside	UDI	Unique device identifier
	GS 1 Data matrix barcode	31	Date (In which medical procedure took place)
	Patient Name		Health care Centre or Doctor
Rx only	Prescription Device	MATERIAL	Material of Construction (Implant Only)
A 文	Translation		Importer
	Distributor	CE 2265 European conformity mark and Identification of Notified Body. The product meets the safety and performance requirements of EU Medical Devices Regulation (EU) 2017/745	
MR	MR Safe		
EC REP	Authorized representative in the European Community		

BASIC UDI-DI : 8903837HML011WR

EC REP

MED DEVICES LIFESCIENCES B.V.
Keizersgracht 482
1017 EG Amsterdam,
The Netherlands
Email:info@meddevices.net
Phone: +31-202254558

Summary of safety and clinical performance (SSCP) is available in the European database on medical devices (EUDAMED), where it is linked to the BASIC UDI-DI : 8903837HML011WR
https://ec.europa.eu/tools/eudamed

Serious incident (s) shall be reported to Healthium Medtech Limited or an in-country representative, and to the health authority where the event occurred.
Email Address: care.sironix@healthiummedtech.com

Healthium

Healthium Medtech Limited
#472-D, 13th Cross, 4th Phase, Peenya Industrial Area,
Bangalore, Karnataka-560058, India
Customer Care No.: 080-41868198
Email Address: care.sironix@healthiummedtech.com
Website: www.healthiummedtech.com
Licence No.: MFG/MD/2021/000378