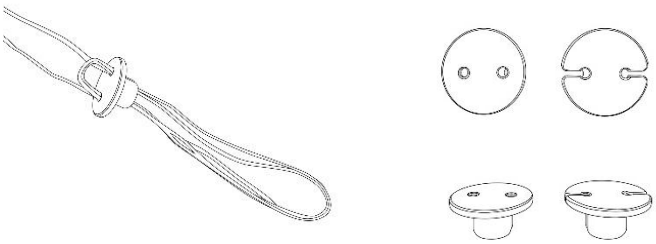
SIRONIX
ArthroscopySolutions

T-BUTTON® A (Closed)
T-BUTTON® S (open)

Cortical Tibial Suspension Fixation Device

PRODUCT INSTRUCTIONS FOR USE (IFU) BOOKLET



PRODUCT DESCRIPTION:

- The T-BUTTON® A/S is a permanently implantable Polyether Ether Ketone (PEEK) cortical tibial suspension fixation device provides the Orthopaedic surgeon a means of accurate suture fixation in ligament reconstructive surgery of soft tissue to bone fixation. The fixation device allows for endoscopic or open ligament reconstruction approaches.
- T-BUTTON® A/S are available in 2 variants open and closed to be used with an adjustable loop or with sutures for suspensory fixation of soft tissue grafts to bone in ligament reconstruction procedures.
- The suture meets applicable specifications for non-absorbable surgical sutures.

MATERIALS SPECIFICATIONS:

Material of Construction: PEEK (Polyether Ether Ketone)
Suture: Braided, UHMWPE Non-Absorbable Suture.
Tape: Braided, UHMWPE Non-absorbable 1.5 mm round-flat-round tape

INTENDED USE:

The fixation device with the sutures incorporated, as components, or without sutures, are intended for surgeries where constructs including those with allograft or autograft tissues are used for fixation of soft tissue to bone during Open or arthroscopic ligament reconstruction procedures.

INDICATIONS:

T-BUTTON® A/S are Indicated in surgical procedures where a combination of a non-absorbable suture and long term wound support is required for soft tissue approximation and/or ligation, including ligament or tendon to bone, or a bone/tendon to bone. See below for specific indications.

Knee: Anterior Cruciate Ligament (ACL) Reconstruction and Posterior Cruciate Ligament (PCL) Reconstruction

CONTRAINDICATIONS:

1. Procedures other than those listed in the INDICATIONS section.
2. Insufficient quantity or quality of bone.
3. Pathologic conditions of bone such as cystic changes or severe osteopenia that would impair its ability to securely fix the anchor
4. Pathological conditions in the soft tissue that would prevent secure fixation of the implant.
5. Blood supply limitations and previous infections, which may retard healing
6. Conditions that tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period.
7. The disc is not designed for and should never be used to attach artificial ligaments.
8. Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantation.
9. The use of this device may not be suitable for patents with insufficient or immature bone. The physician should carefully assess bone quality before performing orthopaedic surgery on patents 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.

INTENDED USERS:

By trained and registered health care professional only.

INTENDED PATIENT POPULATION:

This Implant can be used in patients irrespective of age and sex, in line with the intended use, indications and contraindications.

PERFORMANCE:

PEEK is chemically inert and insoluble, has a modulus of elasticity closer to human cortical bone, and, for sterilization purposes, has high resistance to radiation. Hence, PEEK represents a stable and biocompatible material that may address the issues that are present with titanium screws, such as graft damage because of material hardness and interference with imaging. PEEK Implants do not cause cysts or inflammatory change because of degradation.

UHMPWE 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. UHMPWE suture is not absorbed, nor is it subjected to degradation or weakening by the action of tissue enzymes.

INSTRUCTIONS FOR USE:

For detailed instructions for the usage please see Surgical Technique guide, the following is a summary only.

1. Adequate size tibial and femoral tunnels must be prepared, depending on the diameter of the graft.
2. In tibial tunnel of 8mm or less in diameter it is recommend to expand the distal 1cm of the tibial tunnel to 9mm diameter. This is to accommodate the stub of the T-Button.
3. It is also recommended to clear the soft tissues surrounding the tibial tunnel on the antero-medial tibial cortex to seat the button flush on the bone.
4. Graft passing suture is used to pull the leading and flipping sutures attached to the femoral suspension device from the tibia into the femoral socket. With sustained traction on the leading sutures.
5. The graft is pulled from the tibial tunnel into the femoral socket.
6. The femoral suspension device is flipped as appropriate.
7. The PROLOOP® adjustable loop button (S23-1460-C) is cinched and appropriate length of the graft is pulled into the femoral socket.

Tibial Fixation for T-BUTTON® A:

8. On the tibial side, Flex the knee to about 20o-30o.
9. The adjustable loop of the T-BUTTON® A with the stub facing the tibial tunnel is cinched to reduce the 90mm loop appropriately until you get the appropriate tension in the graft. Make sure that the T-BUTTON® A seats flushes on the tibial cortex.
10. Check the tension in the graft with arthroscopy probe or anterior drawer.
11. The knee is now cycled for 25 cycles of flexion- extension to remove the creep in the graft-fixation device constructed.
12. The graft can now be re-tensioned by cinching the T-BUTTON® A.
13. If desired tension is confirmed, the sutures of the T-BUTTON® A can be knotted with alternate half hitches and the adjustable loop is converted to a fixed loop.
14. Extra length of the cinching suture is cut and removed from the surgical field.

Tibial Fixation for T-BUTTON® S and free Adjustable Loop:

8. After completing the femoral fixation of the graft the free adjustable loop attached to the tibial end of the graft is loaded on the T-BUTTON® S by passing each limb of the adjustable into the slots on either sides of the T-BUTTON® S with the stub facing the Tunnel.
9. Once the Stub of the T-BUTTON® S is seated into the tibial tunnel with the button securely seated on the tibial cortex.

10. The PROLOOP® adjustable loop button (S23-0090-S) is cinched to tension the graft appropriately. As for T-BUTTON® S.
11. The knee is now cycled for 25 cycles of flexion- extension to remove the creep in the graft-fixation device constructed.
12. If desired tension is confirmed, the sutures of the T-BUTTON® S can be knotted with alternate half hitches and the adjustable loop is converted to a fixed loop.
13. Extra length of the cinching suture is cut and removed from the surgical field.

Tibial fixation of T-BUTTON® S with and SIRONIX® Fiber wire

8. The free suture limbs are marked before passing the graft into the femoral socket so that the appropriate sutures of each limb can be knotted.
9. The graft is preloaded by cycling the graft 25 times. Of the eight limbs of the graft, four are passed through one slot of the T-BUTTON® S and the remaining four are passed from the opposite slot.
10. T-BUTTON® S is tensioned by applying sustained pressure on the button with appropriate device while the corresponding sutures are tied with alternate half hitches.

APPLICATIONS:

This Implant can be used in patients irrespective of age and sex, in line with the intended use, indications and contraindications.

WARNINGS:

1. Read these instructions completely prior to use.
2. Appropriate soft tissue clearance should be achieved at the proposed tibial tunnel site to seat the implant flush on the tibia.
3. In case of T-BUTTON® A/S premature traction on the sutures can lead to shortening of the adjustable loop.
4. In case of T-BUTTON® S, non-sliding knots should be used with appropriate tension in order to avoid a graft laxity and eventual failure of surgery.
5. For a successful utilization of this fixation device you need to know the preoperative and operating room procedures, including through knowledge of surgical techniques and proper selection and placement of the implant. It's always recommended that an alternative fixation device and its related instrumentation be available in the event of complication during implantation of T-BUTTON®.
6. Only use SIRONIX® recommended drill bits and drill guides intended for the use with T-BUTTON® A/S. Improper use of instruments may injure patient / damage instruments or compromise fixation.

PRECAUTIONS:

1. Prior to use, inspect the device to ensure it is not damaged. Do not use a damaged device.
2. Users must review and understand the Surgical Technique prior to performing the operation. Only the recommended instrumentation from SIRONIX® should be used to prepare the tibial tunnel for device insertion.
3. Graft preparation and dimensions are specific to the T-BUTTON® A/S and must be followed accordingly.
4. The use of PEEK surgical implants provides the Orthopaedic surgeon with a means of accurate fixation and helps generally in the management of fractures and reconstructive surgery. These implants are intended as aids to normal healing, but are not intended to replace normal body structures or bear the weight of the body in the presence of incomplete bone healing.
5. Exercise maximum care when removing fixation devices with suture from packaging to prevent tangling of sutures and premature deployment of the adjustable loop.

6. Postoperative care is important & a patient should be instructed on the limitations of the implant and should be cautioned regarding weight bearing and body stresses on the appliance prior to secure bone healing.
7. Do not use sharp instruments to manage / control sutures.
8. Do not use T-BUTTON® A/S in sub-optimal tibial tunnel angles and length. Doing so may cause the device to underperform. For further guidance on proper preparation of the tibial tunnel, refer to Surgical technique.
9. Do not use T-BUTTON® A/S in patients with poor bone quality. Doing so may cause the device to pull through the tibia.
10. Do not directly impact the T-BUTTON® A/S implant.

ADVERSE EFFECTS/SIDE EFFECTS:

1. Mild inflammatory reaction
2. Foreign body reaction
3. Infection, both deep and superficial
4. 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
5. Breakage of the device may occur.
6. Loss of fixation or pull-out of the anchor may occur during Implant Loop tensioning.

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. Discard opened, unused device.

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:

3 years from the manufacturing date.

DISPOSAL:

Discard used device in the container meant for infectious waste Unused expired pouches should be incinerated or disposal should be done as per local regulations.

PACKING & LABELING:

1. Please contact the customer service to report any package damage or alterations.
2. All components are packed in protective sterile packaging. Sterile packaging is marked as STERILE with sterilization method.
3. The manufacturer or local distributor cannot accept returned implants except in their original, undamaged and totally intact packaging.
4. If the packaging seal is broken or the packaging is opened improperly, the manufacturer cannot guarantee sterility and cannot be held liable.
5. Before open sterile packaging, check the implant size by verification with preoperative planning.

SYMBOLS:

	Manufacturer		Quantity
	Date of Manufacture with Country of Manufacture		Keep away from sunlight
	Use-by Date		Keep dry
	Batch code		Upper limit of temperature
	Catalog number		Do not re-use
	Sterilized using ethylene oxide		Consult instructions for use
	Do not re-sterilize		Caution
	Do not use if package is damaged & consult instructions for use		Medical Device
	Double sterile barrier system		Unique Device Identifier
	GS 1 Data Matrix Barcode		Date (In which medical procedure took place)
	Patient Name		Health care Centre or Doctor

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

Manufactured at:
Survey No. 388/1, Amsaran –Rohisa Road, Rohisa,
Kheda, Gujarat-387110, India
Licence No.: MFG/MD/2021/000378