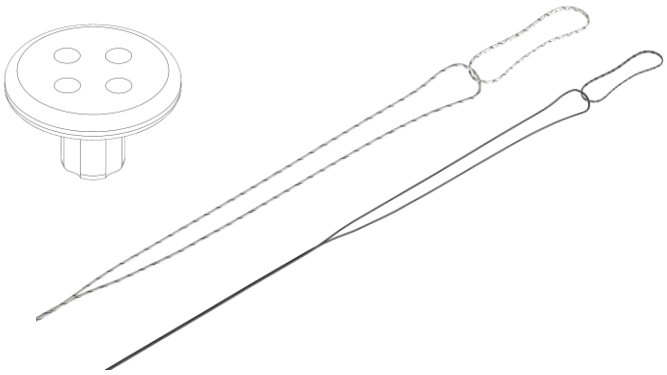
SIRONIX
ArthroscopySolutions

T-Button™ R

Meniscus Root Repair Implant

PRODUCT INSTRUCTIONS FOR USE (IFU) BOOKLET



PRODUCT DESCRIPTION:

The Meniscus Root Repair Implant is a permanently implantable Polyether Ether Ketone (PEEK) fixation device which provides the orthopaedic surgeon a means of accurate fixation in posterior root tear of the medial meniscus. The fixation device allows for endoscopic or open meniscus reconstruction approaches.

MATERIALS SPECIFICATIONS:

T-Button: 100% PEEK (Polyether Ether Ketone)
Loop: Suture- Non-absorbable, UHMWPE USP #1
Tape- Non-absorbable UHMWPE 1.5mm available in Round-Flat-Round

INTENDED USE:

The Meniscus Root Repair Implant is intended for soft tissue fixation to the bone.

INDICATIONS:

The Meniscus Root Repair Implant is indicated for surgeries which require soft tissue fixation to Bone specifically for Meniscus root repair.

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. This device 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 patients with insufficient or immature bone.

INTENDED USERS:

By trained and registered health care professional only.

INTENDED PATIENT POPULATION:

This implant can be used in patients who are skeletally mature as per the treating physician, 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.

Preparation of root repair bed on tibial surface: -

- On identifying the presence and reparability of the meniscal root tear, and other significant pathology in the joint and treated as indicated. prepare the bony bed for the meniscal root attachment on the posteromedial aspect **(4.2 mm to 5.3 mm posteromedial distance from the apex of the Lateral Tibial Eminence, 12.7 mm anterior to the most proximal margin of the PCL's tibial insertion site)** of the tibia by using the shaver blade to debride the scar tissue that may limit the visualization.

A curette in the Meniscal Root Repair System can be used to decorticate the bony area on the posterolateral aspect of the medial tibial plateau where the meniscal root attachment is planned to be re-approximated.

Preparation of the meniscal body

Try to release the scar tissue on both the inferior and superior surface of the meniscus.
It's always recommended to leave some capsule still attached to the meniscus to ensure that there is a good meniscal substances present for the repair.
The meniscus should be regularly grasped with a standard grasper to verify the level of mobility created by the release. Once it is determined that the meniscus is sufficiently released, the next step is to prepare the tunnels

Tunnel preparation

Using root repair jig at required angulation in the right anatomical site as defined earlier, pass the guide wire with the predefined position, later rim the tunnel using the 4.5 reamer till the desired tunnel length.

Passing the suture

Place the meniscal root repair loop in the slot provided in the jaw of meniscal suture passer. Pass the suture passer through the anteromedial porter or anterior lateral portal.
Take the appropriate bite through the posterior horn of the meniscus, Traditional Luggage Tag the loop post the bite. Repeat the same process with the second loop. Shuttle both sutures through the tibial tunnel.
Optional: if required you can separate the suture in sutures by pulling it out from each suture loop.

Loading of T Button R

The suture ends are then passed through the opposite holes of the T Button R, the stub is flushed inside the opening of the tibial tunnel, and a sliding knot (surgical discretion) is created and tightened on the face of the T Button R. Use the knot pusher if the choice of knot is half hitches
The anterior and posterior sutures are shuttled down their respective tunnels. The sutures are tied over a cortical fixation device T Button R.
Using the suture cutter remove the excess suture post knotting and tightening.

APPLICATIONS:

The Implants should be selected and implanted depending on patient's condition, surgical experience, and surgical technique.

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 the device premature traction on the sutures can lead to shortening of the adjustable loop.
4. 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 the device.
5. Improper use of instruments may injure patient / damage instruments or compromise fixation. Only use recommended drill bits and drill guides intended for the use with this device.
6. 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.

7. Device removal should be followed by adequate postoperative management.
8. Postoperatively and until healing is complete, fixation provided by this device should be considered as temporary and may not withstand weight bearing or this device should be protected. The postoperative regimen prescribed by the physician should be strictly followed to avoid adverse stresses applied to the device.
9. Detailed instructions on the use and limitations of the device should be given to the patient.

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. Users must review and understand the Surgical technique prior to performing the procedure. Only the recommended instrumentation for this device should be used to prepare the tibial tunnel for device insertion.
4. Graft preparation and dimensions are specific to this device and must be followed accordingly.
5. This implant and implants in general 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.
6. Exercise maximum care when removing fixation devices with suture from packaging to prevent tangling of sutures and premature deployment of the adjustable loop.
7. 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.
8. Do not use sharp instruments to manage / control sutures.
9. Do not use this device 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.
10. Do not use this device in patients with poor bone quality. Doing so may cause the device to pull through the tibia.
11. Do not directly impact this device.
12. After usage, this device may be a potential biohazard and should be handled in accordance with accepted medical practice and applicable local and national requirement.
13. 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.

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.

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. 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.

SYMBOLS:

	Manufacturer	QTY	Quantity
IN	Date of Manufacture with Country of Manufacture		Keep away from sunlight
	Use-by Date		Keep dry
LOT	Batch code	30°C	Upper limit of temperature
REF	Catalog number		Do not re-use
STERILE EO	Sterilized using ethylene oxide		Consult instructions for use
	Do not re-sterilize		Caution
	Do not use if package is damaged & consult instructions for use	MD	Medical Device
	Double sterile barrier system	UDI	Unique Device Identifier
	GS 1 Data Matrix Barcode	31	Date (In which medical procedure took place)
	Patient Name		Health care Centre or Doctor
		MATERIAL	Material of Construction (Implant Only)

BASIC UDI-DI : 8903837HML065XG

Incident (s) should be reported to Healthium Medtech Limited or an in-country representative, and to the health authority where the event occurred.
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Healthium

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