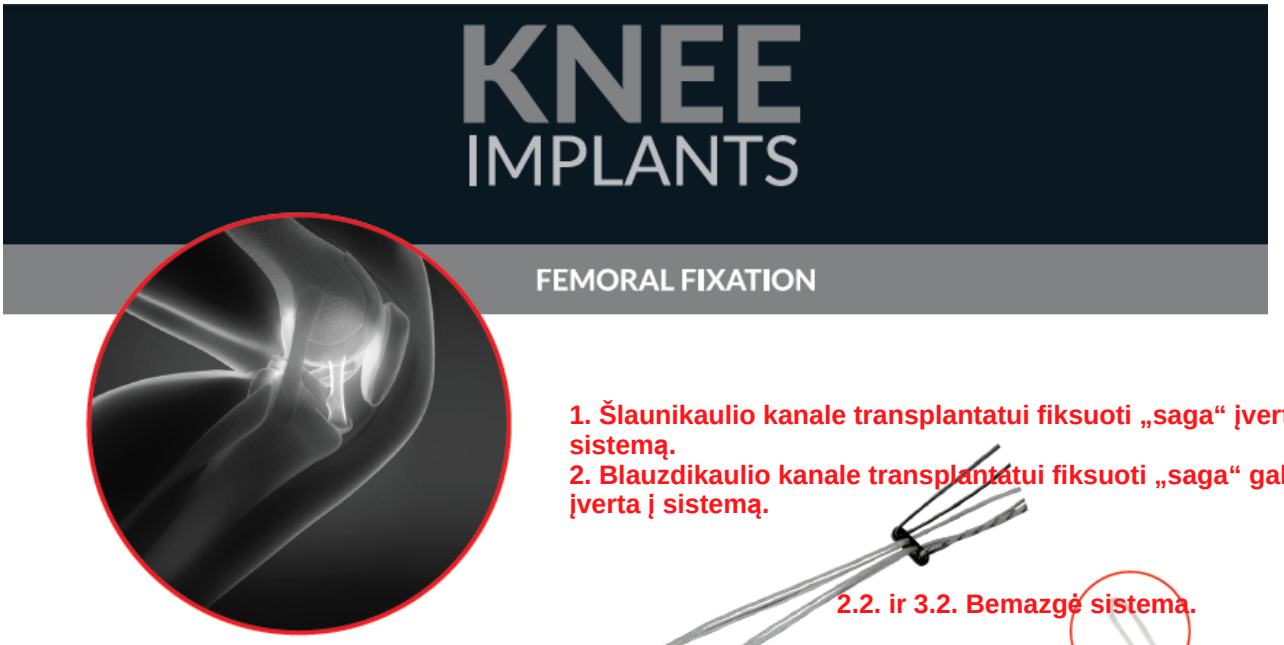
2 ir 3 pirkimo dalis

Sistema skirta rekonstruoti PKR kai transplantatas fiksuojamas šlaunikaulio ir blauzdikaulio kanaluose dviem atskirais „sagos“ formos implantais.



1. Šlaunikaulio kanale transplantatui fiksuoti „saga“ įverta į siūlų sistemą.
2. Blauzdikaulio kanale transplantatui fiksuoti „saga“ gali būti įverta į sistemą.

2.2. ir 3.2. Bemazgė sistema.

2.6. ir 3.6. Sistema užtaisyta su ultra aukštos molekulinės masės polietileno siūlu.

PROLOOP (ULTRA, MINI, XL)

- An adjustable loop button fixation device.
- The loop is made of non-absorbable, braided durable suture (made of Ultra high molecular weight Poly ethylene - UHMWPE) in designed in order to form an adjustable loop giving surgeons the required adjustability of the length
- Proloop provides a double locking plexus at the level of button and the other at the end of the loop.
- The construct has pulling sutures on each side of button for the flipping suture to ensure precision and ease in flipping the button.

2.3. ir 3.3. Savaime užsiveržiančiu principu veikianti slankiojančių siūlų sistema. Siūlų sistema turi galimybę prisitaikyti prie bet kokio kaulo kanalo lygio.

2.7. ir 3.7. atskiras siūlas skirtas ištraukti sagą per kanalą ir ją pozicionuoti.

PROLOOP ULTRA – 2 sizes [14mm button with 60mm/90mm adjustable loop]
PROLOOP MINI – [8mm button with 100mm adjustable loop]
PROLOOP XL – [20mm button with 90mm adjustable loop]

Saga pailgos formos.

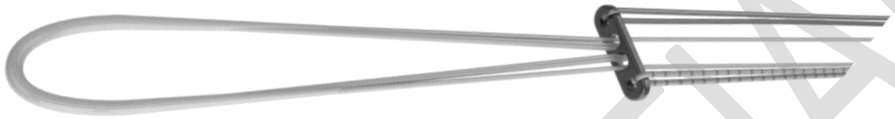
Product Reference No.	Measuring / Test Parameters Button Length (mm)	Measuring / Test Parameters Button Thickness (mm)	Measuring / Test Parameters Button Width (mm)	Measuring / Test Parameters UHMWPE Loop Length (mm)
S23-1460-C	14.00	1.50	4.00	60.00
S23-1490-C	14.00	1.50	4.00	90.00
S23-2090-C	20.00	1.50	4.00	90.00
S23-8100-C	8.00	1.20	2.50	100.00

2.5 ir 3.5. Sagų ilgis 14mm-20mm.
Ne mažiau dviejų dydžių pasirinkimas.

Tinkama „all inside “ artroskopinei technikai“

- **S23- 1460/1490**- C : Suitable for ALL- INSIDE Technique ACL /PCL and standard procedure.
- **S23-2090-C**: Suitable for Revision / Blow-out and Standard ACL/PCL Technique.
- **S23-8100-C**: Suitable for Paediatric Ligament Reconstruction, Multi-Ligament Reconstruction (Collateral Ligament reconstruction/ MPFL)

S23-1460-C	Adjustable Loop UHMWPE Suture Titanium Button-14 x 60 mm
S23-1490-C	Adjustable Loop UHMWPE Suture Titanium Button-14 x 90 mm
S23-2090-C	Adjustable Loop UHMWPE Suture Titanium Button-20 x 90 mm
S23-8100-C	Adjustable Loop UHMWPE Suture Titanium Button-8 x 100 mm



Reference: *Data on file

Disclaimer:

Responsibility for administering products mentioned and interpretation of clinical data provided lies with the registered medical practitioner. For more information about products, their application & precautions please visit www.healthiummedtech.com

To know more scan through your camera

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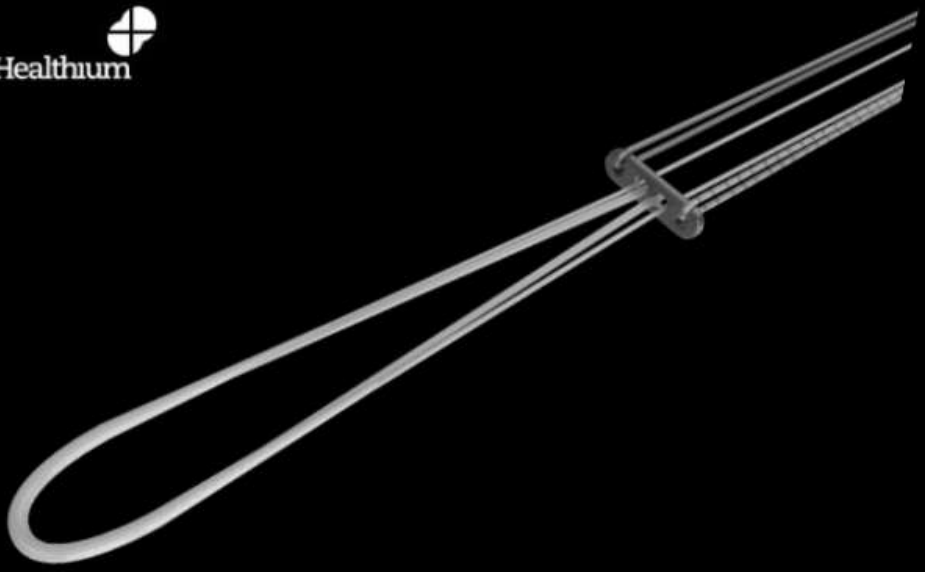
Healthium

EU-MDR



Proloop- Adjustable Button

SIRONIX Arthroscopy Solutions | Healthium

EU-MDR

Adjustable button
> Available in Various sizes
> Double lock mechanics
> Mini button for pediatric surgery
> Big button for revision surgery
>Suture size #5 **2.6 ir 3.6. Sistema užtaisyta #5 UHMWPE siūlu.**

2.4 ir 3.4 Titano lydinio saga.

	ADJUSTABLE LOOP BUTTON
S23-1460-C	Adjustable Loop UHMWPE Suture Titanium Button-14 x 60 mm
S23-1490-C	Adjustable Loop UHMWPE Suture Titanium Button-14 x 90 mm
S23-2090-C	Adjustable Loop UHMWPE Suture Titanium Button-20 x 90 mm
S23-8100-C	Adjustable Loop UHMWPE Suture Titanium Button-8 x 100 mm

SIRONIX

Arthroscopy Solutions

PROLOOP™

Adjustable Loop Button

Product Instructions for Use (IFU) Booklet

PROLOOP™ ADJUSTABLE LOOP BUTTON

1. DEVICE DESCRIPTION

The SIRONIX® PROLOOP™ Adjustable Loop Button fixation device consists of one metal button and sutures strands used for accurate fixation in lower limb ligament reconstructive surgery. The fixation device allows for arthroscopic ligament reconstruction. The implant comes in different button and loop sizes, refer to product label.

MATERIAL

SIRONIX® PROLOOP™ Adjustable Loop Button fixation device is composed of two components : a variable suture loop and a metal fixation device (button). The suture portion of the fixation device is made of a UHMWPE (Ultra-high-molecular-weight polyethylene) suture interwoven in order to from flexible length loop which can be adjusted in length. The fixation device (button) is made of titanium alloy which meets *ASTM F136-13*. The suture meets applicable specifications for non-absorbable surgical sutures

2. INDICATIONS FOR USE

The SIRONIX® PROLOOP™Adjustable Loop Button fixation device is used for fixation of tendons and ligaments during orthopedic reconstruction procedures such as anterior cruciate ligament (ACL), Posterior cruciate ligament (PCL), Medial collateral ligament (MCL) & other ligament to bone fixation surgeries. SIRONIX® PROLOOP™ devices are intended as adjuncts in fracture repair involving metaphyseal and perarticular small bone fragments where screws are not indicated, and as adjuncts in external and intra medullary fixation systems involving plates and rods, with fracture braces and casting.

3. CONTRAINDICATIONS

1. Known hypersensitivity to the implant material. Where material sensitivity is

suspected, appropriate tests should be made and sensitivity ruled out prior to implantation.
2. Insufficient quantity or quality of bone.
3. Pathological conditions of bone, such as cystic changes or severe osteopenia, which would compromise secure fixation.
4. Blood supply and previous infections which may tend to retard healing.
5. Known Active infections.
6. Physical conditions that would eliminate or tend to eliminate adequate implant support or retard healing, i.e. blood supply limitation, previous infection, etc.
7. Conditions which tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period.
8. The use of this device may not be suitable for patients with insufficient or immature bone quality. The treating physician should access the quality of bone before performing orthopedic surgery on patients who are skeletally immature. The use of this device & placement of implants should not bridge, disturb or disrupt the growth plate.
9. Do not use for surgeries other than what is indicated.

4 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 pre-sterile unless package is opened or damaged. DO NOT RESTERLIZE. For single use only. Discard any open, unused product.
3. Do not use after the expiration date.
4. It is the surgeon's responsibility to be familiar with the appropriate surgical techniques prior to use of this device.
5. Read these instructions completely prior to use
6. Only use SIRONIX® recommended drill bits and drill guides intended for the use with SIRONIX® PROLOOP™ Adjustable Loop Button. Improper

use of instruments may injure patient / damage instruments or compromise fixation.

7. As with any foreign body, prolonged contact of this suture with salt solutions, such as those found in urinary and biliary tracts, may result in calculus formation.
8. **Biohazard waste**, such as explanted devices, needles and contaminated surgical equipment, should be safely disposed of in accordance with the institutions policy.

5. PRECAUTIONS

1. Regulations restrict this device to sale by or on the order of a physician.
2. Hazards associated with reuse of this device include, but are not limited to, patient infection and/or device malfunction.
3. Prior to use, inspect the device to ensure it is not damaged. Do not use a damaged device.
4. The use of metallic surgical implants provides the orthopedic 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. Ensure the arthroscopic cannulated reamer(other than 4.5mm) does not breach the femoral cortex, otherwise the femoral fixation with the fixation device will be compromised.
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. Careful attention must be paid to asepsis and avoidance of anatomical hazards.
8. After use, this device may be a potential biohazard and should be handled in accordance with accepted medical practice and applicable local and national

requirements.

9. Do not use sharp instruments to manage / control sutures.

6. ADVERSE EFFECTS

Complications are those seen with any method of internal fixation. Adverse reactions associated may include ;

1. Mild inflammatory reaction
2. Foreign body reaction
3. Infection, both deep and superficial
4. Allergic reaction
5. Metal implants only : dislocation/subluxation

7. INSTRUCTIONS FOR USE

1. Drill a calibrated passing pin through the SIRONIX® Femoral Aimer and the lateral cortex of the femur
2. Drill over the previously placed passing pin,the femoral tunnel with the 4.5 mm arthroscopic cannulated drill bit through the lateral cortex of the femur, Pass the 4.5 mm drill in and out of the cortex two to three times to facilitate passage of the implant.
3. Drill over the previously placed passing pin, with an endoscopic reamer corresponding to the diameter of the graft and ream to the depth that will allow the desired soft-tissue graft-to-tunnel interface.
4. Measure the total femoral channel length using the graduated markings on the SIRONIX® depth gauge.
5. Determine the estimated graft insertion lengths for the tibial tunnel and femoral socket appropriately.
6. Load the Graft through the loop of the SIRONIX® Proloop™ -Adjustable loop button.
7. Mark the appropriate tunnel length on prepared graft.
8. Mark the tunnel length marking on the loop to aid during flipping stage, also

mark a point on cinching sutures to aid in coordinated cinching.

9. Pass the Cinching sutures (complete white), Pulling sutures (White with Black strand) & Flipping (Black with White strands) sutures through a passing loop for tunnel passage.
10. Using pulling sutures, pull the button through the femoral tunnel, while maintaining consistent tension on cinching and flipping suture, until the tunnel length marking on the loop is inside the femoral tunnel.
11. At this stage using flipping sutures flip the button on the femoral cortex, while maintaining counter tension on graft from tibial side.
12. After the button is firmly seated on femoral cortex, start cinching the adjustable loop by pulling the cinching sutures in cinching/alternating pulls of each of the cinching suture, while maintaining counter tension on graft from tibial side.
13. While holding close to the joint space ensure coordinated cinching.
14. Cinch up to appropriate length of loop and graft inside femoral tunnel is achieved.

8. WARRANTY

This product is warranted to be free from defects in material and workmanship. Do not reuse.

9. STORAGE

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.

10. STERILIZATION

The SIRONIX® PROLOOP™ Adjustable Loop Button Fixation device is provided presterile. Do not re-sterilize.

11. FOR FURTHER INFORMATION

If further information on this product is needed, contact SIRONIX® Arthroscopy Solutions Customer Service or an authorized representative.

12. PACKING & LABELING


Do not reuse

Batch number


Mfg. Date


Exp. Date


Manufacturer


Humidity Limitation

Sterilized using Ethylene oxide


Handle with Care


Upper limit of temperature


Caution


Keep dry


Keep away from sunlight


Do not resterilize


Consult instructions for use


Do not use if package is damaged

2.1 ir 3.1 sterilioje pakuotėje.

Shelf Life : 3 Years

PROLOOP™: IFU V03 | Date : 01/NOV/2021

SIRONIX

Arthroscopy Solutions

Manufactured and Marketed by:

Healthium

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Mfg. Lic. No. : MFG/MD/2021/000378