MENISCUS REPAIR: ALL INSIDE

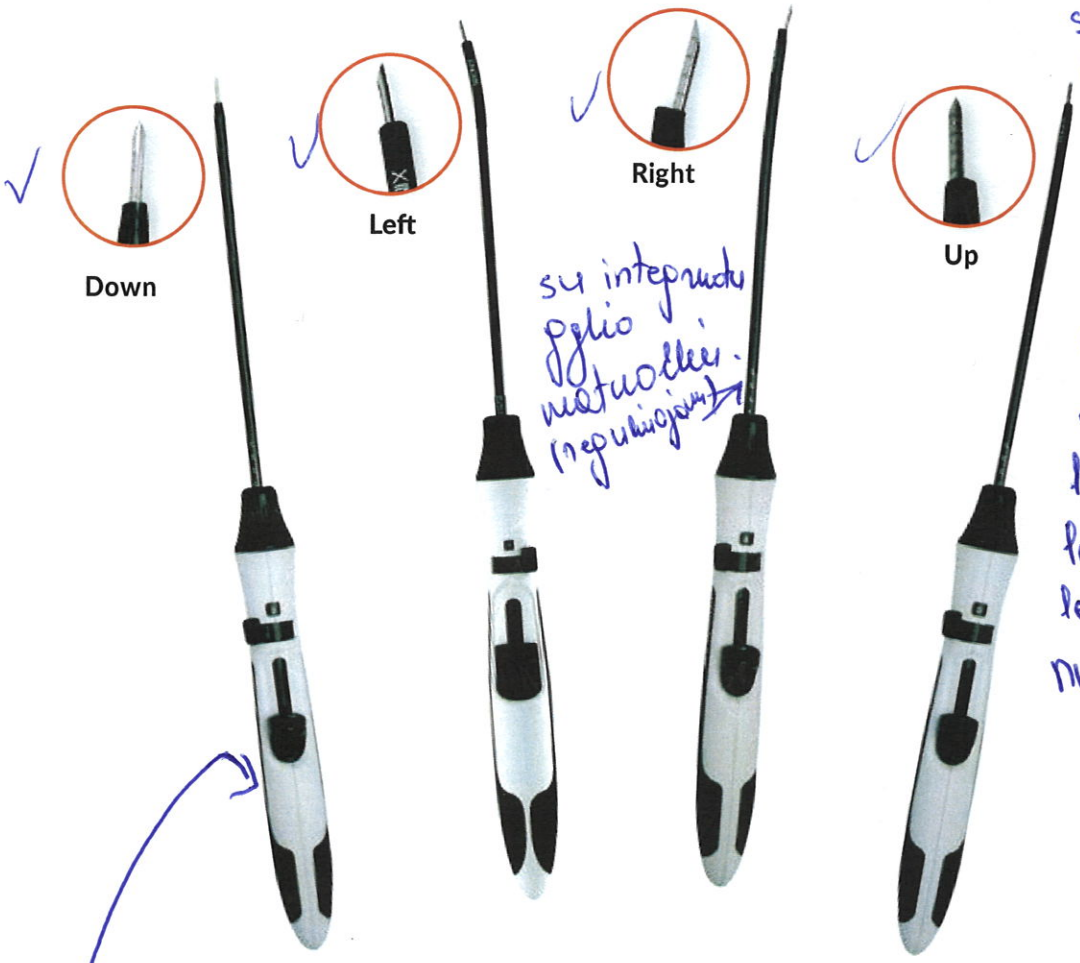
SIRONIX
Arthroscopy Solutions

Catalogue No.	Description
S29-1700-TQ	Sure Stitch Open Cannula
S29-1701-TQ	Sure Stitch Suture Cutter
S29-1702-TQ	Sure Stitch Diamond Rasp
S29-1703-TQ	Sure Stitch Meniscus Depth Gauge
✓ S29-1800-TQ	UHMWPE Suture PEEK Button Meniscus Repair Implant-Up
✓ S29-1801-TQ	UHMWPE Suture PEEK Button Meniscus Repair Implant-Left
✓ S29-1802-TQ	UHMWPE Suture PEEK Button Meniscus Repair Implant-Right
✓ S29-1803-TQ	UHMWPE Suture PEEK Button Meniscus Repair Implant-Down
S29-1804-TQ	UHMWPE Suture PEEK Button Meniscus Repair Implant-XL-Up
S29-1807-TQ	UHMWPE Suture PEEK Button Meniscus Repair Implant-XL-Left
S29-1808-TQ	UHMWPE Suture PEEK Button Meniscus Repair Implant-XL-Right
S29-1809-TQ	UHMWPE Suture PEEK Button Meniscus Repair Implant-XL-Down
S29-1805-TQ	SureStitchCombo Pack-1 (3 Sure Stitch)
S29-1806-TQ	SureStitchCombo Pack-2 (Combo-1 plus 2 instruments)

4 Pirkimo dalis Meniscо susiuvimo sistema

UHMWPE (ultra aukštos masės polietilenas)

„T" inkaro cheminė sudėtis – PEEK (Polieter-eter-ketonas).



su integruotu gijos matuokliu (reguliuojamu)

Pravedimo adata: lenkta į viršų, lenkta į dešinę, lenkta į kairę, nukreipta žemyn.

Features*:
- Anchor design provides benefits of bone preservation.
- UHMWPE Suture material.
- Unique tri-pod bunched pattern doubles up compared to the original size.
- Gives higher pull out strength.

vienkartinis ergonomiškos formos cilindro formos įvedimo instrumentas.

1

INKARO IŠMATAVIMAI:

Product Reference No.	Measuring / Test Parameters	Measuring / Test Parameters	Measuring / Test Parameters
	Peek Implant-1 Length	Peek Implant-2 Length	UHMWPE Suture Length
S29-1800-TQ	5,50	6,40	290
S29-1801-TQ	5,50	6,40	290
S29-1802-TQ	5,50	6,40	290
S29-1803-TQ	5,50	6,40	290
S29-1804-TQ	5,50	6,40	290

1. Įkaras – 5,5 mm.
2. Įkaras – 6,4 mm.

UHMWPE
siūlo ilgis – 290mm.

SURESTITCH is designed for accuracy, reliability, and ease of use in surgical procedures.

Reguliuojamas pjūvio matuoklis

17-Gauge Stiff Needle

Ensures ease in piercing for smooth and efficient suturing.

Adjustable Depth Control

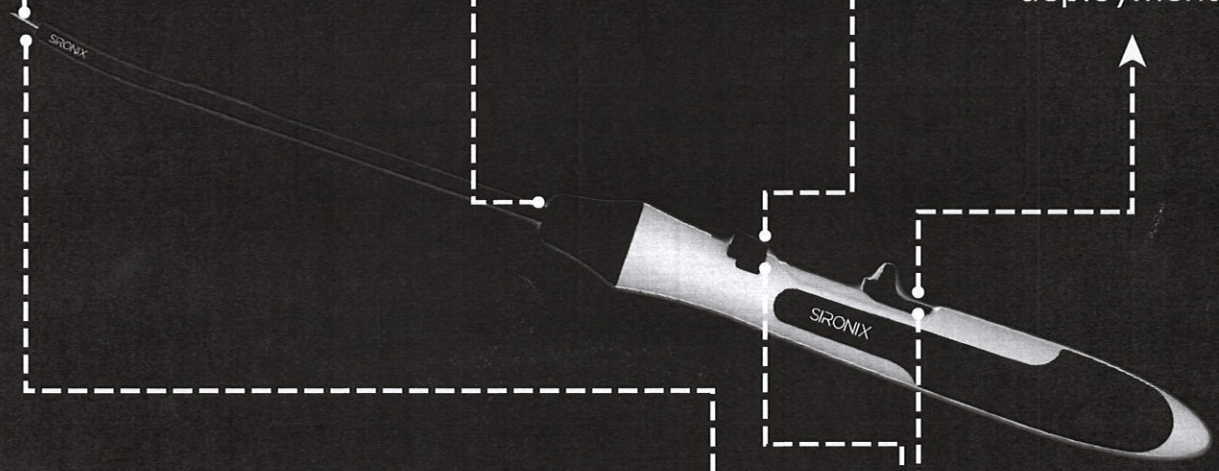
Allows surgeons to deploy at the desired depth with precision.

Safety Knob

Prevents misfire for enhanced procedural safety.

Audible Click

Provides confirmation of secure deployment.



Ergonomiškas formos

ERGONOMIC DESIGN
enables one-handed use with a simple 3-step PTF deployment process.

Pierce
The Needle

Turn
The Safety Knob

Fire
The Implant

ORDERING INFORMATION

Code	Description
S29-1800-TQ	Sure Stitch Meniscus Repair Implant
S29-1801-TQ	Sure Stitch Meniscus Repair Implant Left
S29-1802-TQ	Sure Stitch Meniscus Repair Implant Right
S29-1803-TQ	Sure Stitch Meniscus Repair Implant Down
S29-1805-TQ	SureStitchCombo Pack-1 (3 Sure Stitch)
S29-1806-TQ	SureStitchCombo Pack-2 (Combo-1 plus 2 instruments)
S29-1811-TQ	Meniscus Repair Implant XI-Flexi

ASSOCIATED INSTRUMENTS

Code	Description
S29-1700-TQ	Sure Stitch Open Cannula
S29-1701-TQ	Sure Stitch Suture Cutter
S29-1702-TQ	Sure Stitch Diamond Rasp
S29-1703-TQ	Sure Stitch Meniscus Depth Gauge

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HL_B2_V2_12Mar2024

Reference: *Data on file

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SIRONIX
ArthroscopySolutions

SURESTITCH

UHMWPE Suture PEEK Button Meniscus Repair Implant

PRODUCT INSTRUCTIONS FOR USE (IFU) BOOKLET

PRODUCT DESCRIPTION:

The UHMWPE Suture PEEK Button Meniscus Repair Implant is an all-inside meniscal repair device with two PEEK non-absorbable polymer implants, preloaded with UHMWPE sutures. The UHMWPE Suture PEEK Button Meniscus Repair Implant is preloaded with USP #3-0 UHMWPE suture whereas UHMWPE Suture PEEK Button Meniscus Repair Implant XL is preloaded with USP #2-0 suture. The adjustable depth control knob is used to define the needle piercing length in the meniscus prior to deployment of the implant. These meniscal repair devices are available in various needle curvature.

MATERIALS SPECIFICATIONS:

Implant	: 100% pure 2 PEEK (Polyether Ether Ketone) implants
Suture	: Non-absorbable, UHMWPE USP #3-0 (UHMWPE ≥ 99.45% & Black Colour ≤ 0.55%)
Driver Shaft	: Stainless steel (SS 300 Series)
Driver Handle	: ABS (Acrylonitrile Butadiene Styrene)
Holding Tube	: Transparent Silicon tube (Medical Grade)
Depth Control Tube	: PEBAX Black Colour (Medical Grade)

VARIANTS:

- UHMWPE Suture PEEK Button Meniscus Repair Implant Left
- UHMWPE Suture PEEK Button Meniscus Repair Implant Right
- UHMWPE Suture PEEK Button Meniscus Repair Implant Up
- UHMWPE Suture PEEK Button Meniscus Repair Implant Down
- UHMWPE Suture PEEK Button Meniscus Repair Implant XL-Up
- UHMWPE Suture PEEK Button Meniscus Repair Implant XL-Left
- UHMWPE Suture PEEK Button Meniscus Repair Implant XL-Right
- UHMWPE Suture PEEK Button Meniscus Repair Implant XL-Down

INTENDED PURPOSE:

The UHMWPE Suture PEEK Button Meniscus Repair Implant is intended for use as a suture retention device to facilitate percutaneous or endoscopic soft tissue procedures such as, meniscal rupture.

INDICATIONS:

The UHMWPE Suture PEEK Button Meniscus Repair Implant is intended for Meniscus 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 implant.
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 implant 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:

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. PEEK itself does not encourage bone ingrowth or on growth, but it can be reinforced with elements such as hydroxyapatite, carbon, and tricalcium phosphate, which can encourage bony incorporation. PEEK has poor osseointegration.

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. Assess the reparability and anteroposterior length of meniscus using a graduated probe.
2. Adjust the needle's depth by rotating the depth control knob depending on the meniscus thickness.
3. Using the slotted cannula, slide in the UHMWPE Suture PEEK Button Meniscus Repair Implant up to the meniscus in the inverted position.
4. Pierce the meniscus at the desired point until the depth control tube touches the meniscus.
5. Now prepare to deploy the first implant by turning the safety knob from safe position "0" to active position "1".
6. Advance the deployment knob fully using the thumb to deploy the first implant, until there's an audible click, then release and allow it to spring back to a pre-specified position.
7. To prepare for the second implant, retract the needle and position it at next desired point until the depth control tube touches the meniscus.
8. Then turn the safety knob to active position "2" and advance the implant using the deployment knob until there's an audible click.
9. Carefully retract the UHMWPE Suture PEEK Button Meniscus Repair Implant from the operating field.
10. Use the Knot pusher to pull the suture tail with consistent tension until the desired approximation of meniscus is achieved. Then cut the remaining suture tail.
11. Use another UHMWPE Suture PEEK Button Meniscus Repair Implant if required for larger meniscus tears.

1. MENISCAL REPAIR ACCESSORIES (sold separately)

Certain associated instruments for the UHMWPE Suture PEEK Button Meniscus Repair Implant are sold separately. Read the instructions for Use, that are enclosed with the instrument(s) prior to use.
Accessories
• Slotted Delivery Cannula and Knot Pusher/Suture Cutter Set (sterile)

Accessory Instrumentation
Certain other instrumentation is associated with the completion of any meniscal repair and/or reconstruction procedure. Those instruments may include, but are not limited to:
• Meniscal depth probe
• 45° diamond rasp

• 90° diamond rasp
These instruments must be properly cleaned, inspected, and sterilized prior to each use. Read the manufacturer's instructions for use prior to use.

EXPLANTATION:

1. Carefully identify the UHMWPE suture and the 2 PEEK implants.
2. Cut the UHMWPE sutures which will loosen the PEEK implants, and then the PEEK implants and UHMWPE suture material is removed by applying outward pressure using a tissue grasper.

APPLICATIONS:

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

CLINICAL BENEFITS:

1. Meniscal repair with or without anterior cruciate ligament reconstruction with mean follow-up of 59 months (16–84) showed excellent Lysholm score in 72% of patients and good in 27% of the patients. The IKDC score was excellent for 81% of the patients and good for 18% of the patients. There were no failures or complications.
2. Meniscus repair cases were examined for Lysholm score, Tegner activity score and radiographic evaluation with an average of 3 years of follow up. Results showed no symptoms of meniscal tears in 96% of the cases.
3. Patients who underwent meniscal repairs were followed up for 30.7 months (range, 12 to 58 months). The preoperative and postoperative Lysholm and Cincinnati, scores were 47.3 and 87.4,38.7 and 82.8, respectively. Improvement was seen in Clinical outcome measures.
4. Upon 12 years of follow up post meniscal repair in isolated meniscal tears and combined tears with a concomitant anterior cruciate ligament rupture the outcome measures indicated no significant difference between isolated and combined group ($p = 0.582$). In isolated and combined injury groups there was no difference in the TAS ($p > 0.05$). There was no significant difference regarding the meniscal repair failure rate when comparing the groups of simultaneous and delayed ACL repair ($p = 0.521$).
5. Post meniscus repair using all inside meniscal repair implant the outcomes recorded at follow up indicated, the mean (SD) of the total IKDC score at baseline and post-surgery was 51.4 (2.84) and 91.8 (2.59) out of 100, respectively. The mean (SD) of TAS pre-injury and post-surgery was 5.3 (1.47) and 5.4 (1.38) out of 10, respectively. The total mean (SD) value of the total Lysholm Score at baseline and post-surgery was 53.9 (3.72) and 91.4 (3.61) out of 100, respectively. The mean (SD) value of the quality-of-life subscale of the KOOS score was 91.2 (3.91) out of 100. There were no adverse device effects reported in this study.
6. The meniscus repair implant comes with a 17-gauge stiffer needle that ensures effortless piercing and a built-in adjustable depth control sheet to prevent over insertion.
7. The meniscus repair implant comes with different angle needle tip which allows for ease of insertion and negotiate easily within intraarticular space thereby reducing the risk of neurovascular injury and skin complications.
8. The meniscus repair implant comes with a safety knob which prevents misfiring, and the audible and visual confirmation ensures sequential implant selection. It has an audible click feature that ensures implant deployment feedback and its ergonomic design enables single handed use.

LIMITATIONS:

1. The All Inside Meniscus Repair surgery involving UHMWPE Suture PEEK Button Meniscus Repair Implant is technically demanding: Some experience in arthroscopic surgery and creation of additional portals maybe required. It increases the surgical time and often a learning curve is required by the surgeon.
2. Possibility of suture hook breakage in "more demanding" places of medial meniscus.

WARNINGS:

1. Surgeon using this shall be familiar with the appropriate surgical techniques prior to use of this product.
2. Do not bend the delivery needle. The UHMWPE Suture PEEK Button Meniscus Repair Implant are manufactured with curved delivery needles. Intentional bending of the delivery needle may make it

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YouTube LT

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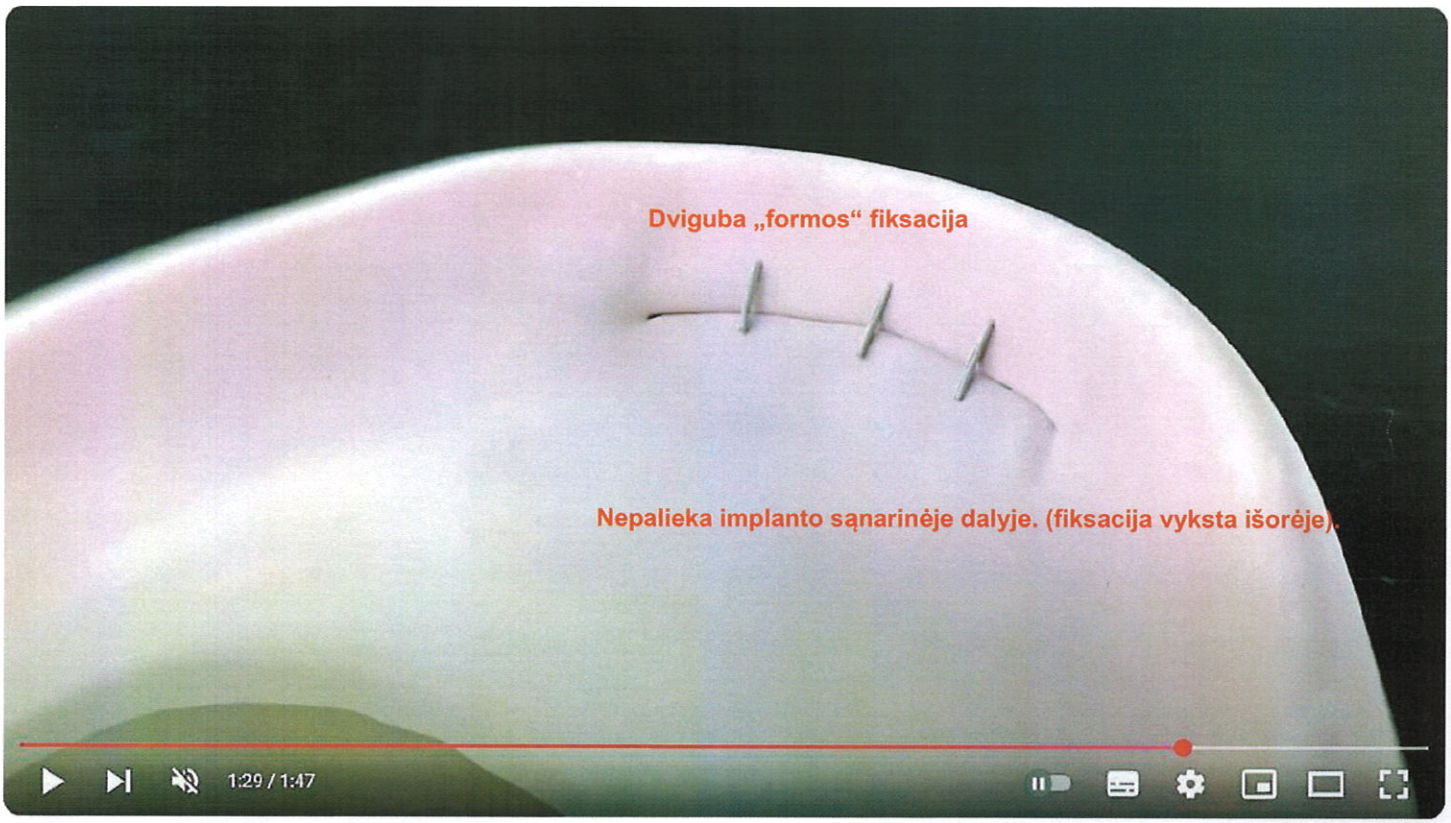
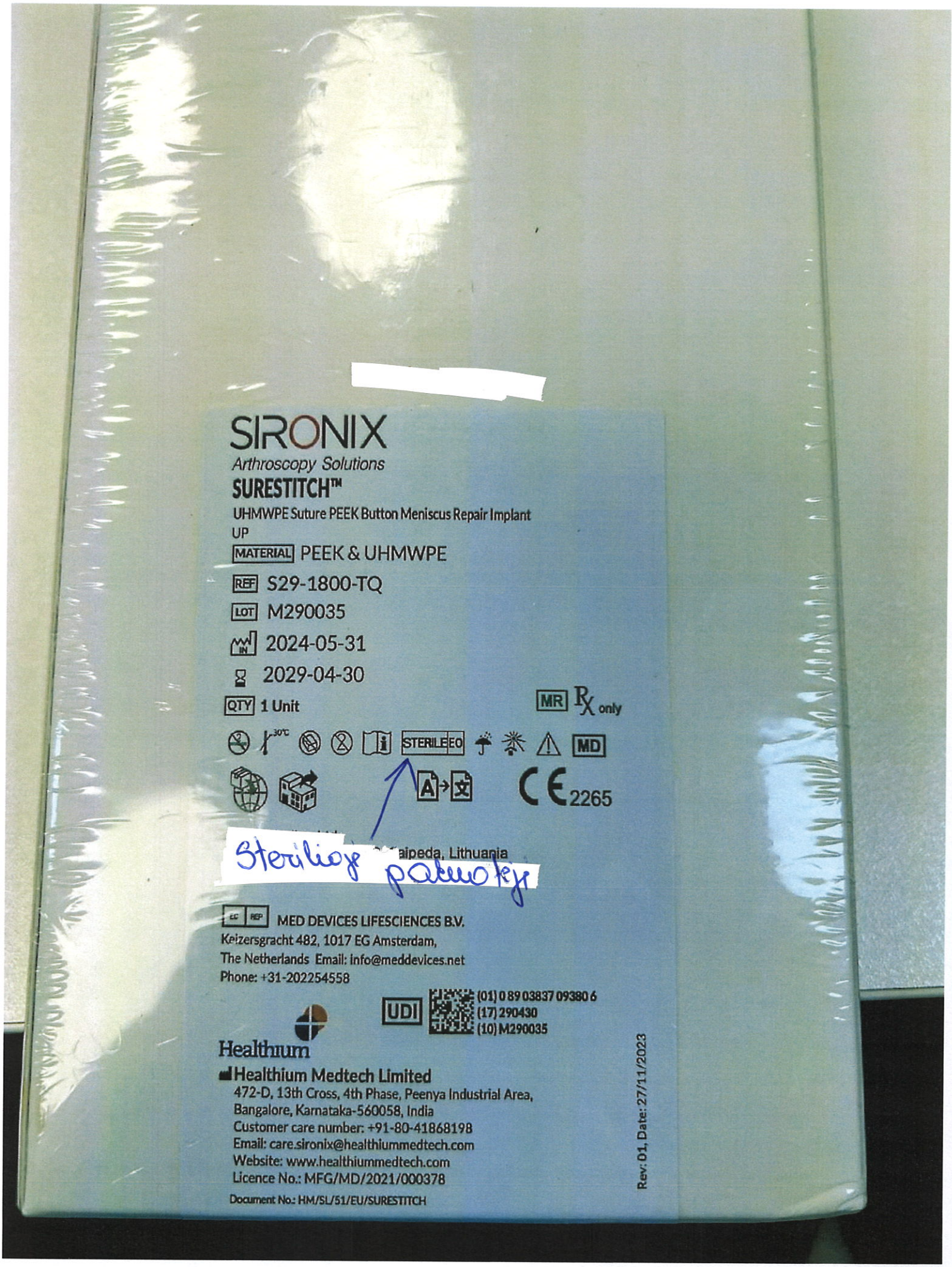


SureStitch All Inside Meniscal repair device


SIRONIX
Arthroscopy Solutions
SURESTITCH™
UHMWPE Suture PEEK Button Meniscus Repair Implant
UP
MATERIAL PEEK & UHMWPE
REF S29-1800-TQ
LOT M290035
2024-05-31
2029-04-30
QTY 1 Unit
MR Rx only
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