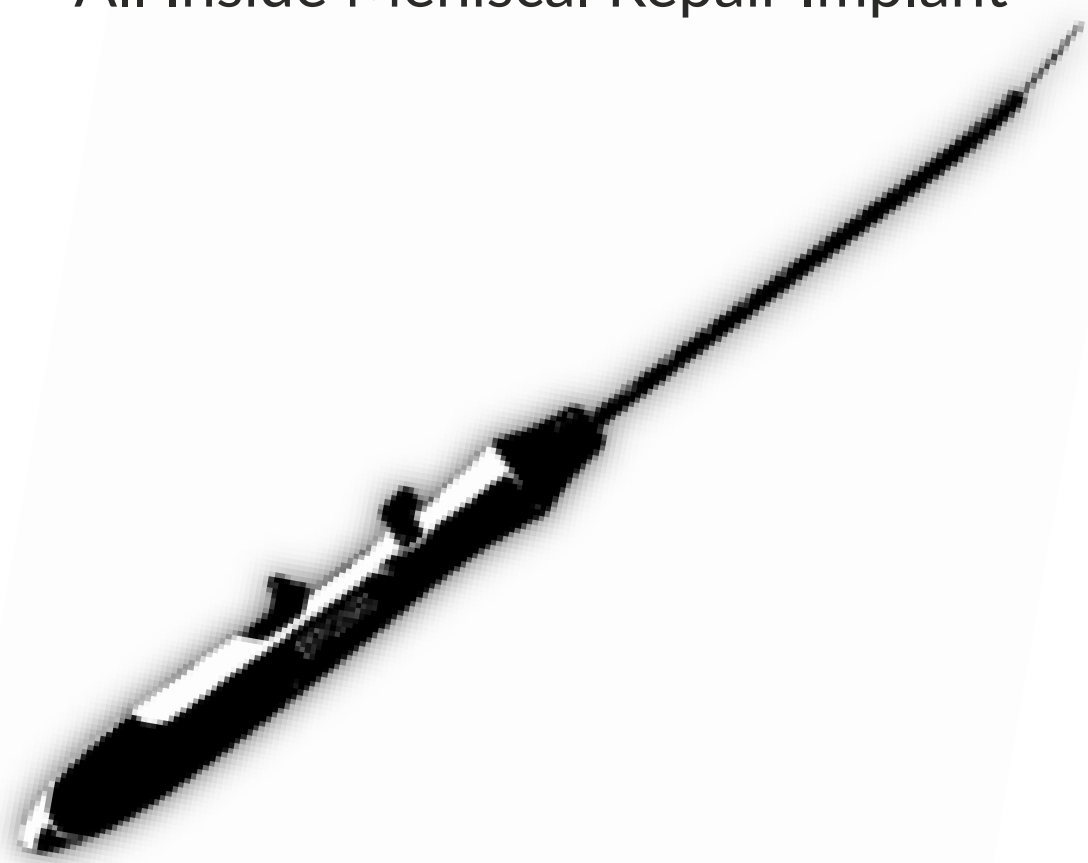
SIRONIX

Arthroscopy Solutions

SureStitch™

All Inside Meniscal Repair Implant



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

SureStitch™ - All Inside Meniscal Repair Implant

1. DESCRIPTION

The SureStitch™ is an all-inside meniscal repair implant, each product includes two non-absorbable implants, pre-tied with #2-0 non-absorbable UHMWPE suture and preloaded into a needle delivery system. Delivery assembly provided sterile for single use only.

Materials

Implant : 2 PEEK (Polyether ether ketone) implants

Suture: #2-0, braided, uncoated, Ultra high molecular weight polyethylene (UHMWPE)

Sironix® Slotted Delivery Cannula and Knot Pusher/ Suture Cutter Set provided sterile for single use only

2. INDICATIONS FOR USE

The SureStitch™ - All Inside Meniscal Repair Implant is intended for use;

1. As a suture retention implant to facilitate percutaneous or arthroscopic soft tissue procedures.
2. For Meniscal repairs and allograft transplant procedures.
3. For anchoring the allograft to the meniscal rim during allograft transplant procedures.

3. CONTRAINDICATIONS

1. Procedures other than those listed in the INDICATIONS section.
2. Pathological conditions in the soft tissue that would prevent secure fixation of the implant.
3. Known hypersensitivity to the implant material. Where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantation.
4. Physical conditions that would eliminate or tend to eliminate adequate implant support or retard healing, i.e. blood supply limitation, previous infection, etc.

5. Conditions which tend to limit the patient's ability to restrict activities or follow directions during the healing period.

4. WARNINGS

- Do not use if package is damaged. Do not use if the product sterilization barrier or its packaging is compromised.
- Contents are sterile unless package is opened or damaged. DO NOT RESTERILIZE. For single use only.
- Discard any open, unused product. Do not use after the expiration date.
- It is the surgeon's responsibility to be familiar with the appropriate surgical techniques prior to use of this product.
- Read these instructions completely prior to use.
- Do not bend the delivery needle. The SureStitch™ implants are manufactured with curved delivery needles. Intentional bending of the delivery needle may make it difficult or impossible to deliver the implants. If the delivery needle has been inadvertently bent, or if resistance is encountered during deployment, a new delivery unit may be needed.
- Do not push the turn the safety knob or deployment knob until the needle is fully penetrated through the meniscus to the appropriate or desired depth.

5. PRECAUTIONS

- National / International laws restrict this product to sale by or on the order of a physician.
- Hazards associated with re-use of this product include, but are not limited to, patient infection and/or product malfunction.
- Prior to use, inspect the product to ensure it is not damaged. Do not use a damaged product.
- Careful attention should be paid to asepsis and avoidance of anatomical hazards.
- A surgeon should not begin clinical use of the SIRONIX® SureStitch™ Knotless Anchor without reviewing the instructions for use and practicing the procedure in a skills laboratory.

- After use, this product may be a potential biohazard/ sharps hazard and should be handled in accordance with accepted medical practice and applicable local and national requirements.

6. ADVERSE REACTIONS

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

1. Mild inflammatory reaction
2. Foreign body reaction
3. Infection, both deep and superficial
4. Allergic reaction

7. 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 SIRONIX® slotted cannula, slide in the SIRONIX® SureStitch™ 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 SIRONIX® SureStitch™ from the operating field
10. Use the Sironix 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 SIRONIX® SureStitch™ implant if required for larger meniscus tears.

CAUTION: After use, this product may be a potential biohazard/ sharps hazard and should be handled in accordance with accepted medical practice and applicable local and national requirements.

8. SIRONIX® SURESTITCH™ MENISCAL REPAIR ACCESSORIES (sold separately)

Certain associated instruments for the **SIRONIX® SureStitch™ - All Inside Meniscal Repair Implant** are sold separately and are provided sterile. Read the Instructions for Use, that are enclosed with the instrument(s) prior to use.

Accessories
SIRONIX® SureStitch™ 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.

9. WARRANTY

For single use only. This product is warranted to be free from defects in material and workmanship. DO NOT RE-USE.

10. 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.

11. STERILIZATION

The SIRONIX® SureStitch™ is provided sterile. DO NOT RE-STERILIZE.

12. FOR FURTHER INFORMATION

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

13. 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

MR **MR (magnetic resonance)** safe

Shelf Life : 3 Years

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

SIRONIX

Arthroscopy Solutions

Manufactured and Marketed by:

Healthium

Healthium Medtech Ltd.
472-D, 13th Cross, 4th Phase, Peenya Industrial Area, Bangalore - 560058, India.
Customer Care No. : 080 - 41868198
Consumer Care Address : Same as Above
Email : care.sironix@healthiummedtech.com

Manufactured at :
Survey No. 388/1, Amsaran - Rohisa Road, Rohisa., Kheda, Gujarat (India) - 387110
Mfg. Lic. No. : MFG/MD/2021/000378