FiberStitch™ Meniscal Repair Device Patient Information Leaflet

Arthrex®

Helping Surgeons Treat Their Patients Better™

Since its inception, Arthrex has been committed to one mission: Helping Surgeons Treat Their Patients Better.™ We are strategically focused on constant product innovation through scientific research, surgeon collaboration, and medical education to make less invasive surgical procedures simpler, safer, and more reproducible. Each year, we develop more than 1000 new innovative products and procedures to advance minimally invasive orthopedics worldwide.

Arthrex has always remained a privately-held company, which allows for the rapid evaluation of new technologies and ideas. Our economic strength enables us to develop products and techniques that truly make a difference without compromising on quality. Our experienced team of dedicated professionals represents a shared passion and commitment to delivering uncompromising quality to the health care providers who use our products and the millions of patients whose lives we impact.

The medical significance of our contributions serves as our primary benchmark of success and will continue into the future as the legacy of Arthrex.

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Introduction

This Patient Information Leaflet is presented by TAG Medical Products Corporation Ltd and provides information that will assist your physician in a discussion regarding the implantation of the device described.

This Patient Information Leaflet contains the list of device variants presented by TAG Medical Products Corporation Ltd. Patient results may vary. Please consult your physician to determine if this device is right for you.

For more information about TAG Medical Products Corporation Ltd devices and their specific materials, or prescribing information, including warnings and contraindications, please read the device labeling.

Device Description and Materials

What is FiberStitch?
The FiberStitch™ device is an all-inside meniscal repair device.

The FiberStitch™ Meniscal Repair Device is intended for use as a suture retention device to facilitate arthroscopic soft tissue procedures. The FiberStitch™ Meniscal Repair Device is indicated for use in meniscal repair procedures.

FiberStitch™ Meniscal Repair Device
The FiberStitch™ includes two non-absorbable polyester implants, pre-tied with #2-0 non-absorbable sutures and preloaded into a needle delivery system. The adjustable depth penetration limiter is preset to approximately 18 mm from the tip of the needle. It can be adjusted down in 2 (mm) increments to approximately 10mm.

The FiberStitch implant is an all-inside meniscal repair system that replaces hard PEEK implants with soft suture sheaths. 2-0 coreless FiberWire® suture and a pretied sliding knot provide secure arthroscopic all-suture meniscus repair. The ergonomic handle is designed for single-handed implant delivery and active implant deployment technology minimizes needle exposure beyond the meniscus, eliminating the need to past-point the needle.

Implant Materials
- Suture: #2-0 FiberWire Ultra High Molecular Weight Polyethylene (UHMWPE), Polyester, Silicone elastomer coating. Dye: D&C Blue No. 6. The #2-0 FiberWire suture meets USP requirements except for diameter.
- Anchor: #4-0 and #6-0 suture - Braided Polyester nonabsorbable, uncoated. Dye: D&C Green No. 6.
- Handle: ABS
- Shaft: Stainless Steel
- Depth Limiter: HDPE

The sutures supplied meet or exceed U.S. and European Pharmacopeia standards for non-absorbable surgical sutures (except for diameter requirements). The suture dyes may include: D&C Blue No. 6, D&C Green No. 6, and Logwood Black.

Refer to the section on the implant models for specific configurations found within this Patient Information Leaflet.

Intended Purpose

This section of the Patient Information Leaflet describes where the meniscal repair device that your physician prescribes can be used in:

- The **FiberStitch™ meniscal repair device** is intended for use as a suture retention device to facilitate arthroscopic soft tissue procedures.
- The **FiberStitch meniscal repair device** is indicated for use in meniscal repair procedures.

To learn more about the diagnosis and treatment of soft-tissue injuries, please visit https://www.orthoillustrated.com/. OrthoIllustrated® is a leading internet-based resource for patient education.

Contraindications

The Meniscal Repair Device is NOT intended for use where one or more of the following conditions exist:

1. Pathological conditions in the soft tissue that would prevent secure fixation.
2. Any active infections.
3. Conditions which tend to limit the patient's ability or willingness to follow postoperative care instructions.
4. Tears to the white zone of the meniscus. Only tears to the red zone of the meniscus, or at most to the transitional zone between red and white, would be candidates for repair.

Risks/Adverse Effects

1. Patient sensitivity to the device materials should be considered prior to implantation. Possible Adverse Effects include.
   - Infection, both deep and superficial.
   - Foreign body reactions.
   - Breakage of the device may occur.
   - Loss of fixation or pull-out of the anchor may occur during Implant Loop tensioning.
2. The materials and manufacturing processes associated with these TAG Medical Products Corporation Ltd devices have been analyzed for residuals. There are no significant health risks from materials or processing residuals based on the analysis.

Pre and Postoperative Care

- Pre-operative and operating procedures, including knowledge of surgical techniques and proper selection and placement of the device, are important considerations in the successful utilization of this device.
- Your Physician should advise on the appropriateness of the surgery and choice of implant that will be best suited for your condition.
- Postoperative management is patient-specific and dependent on your doctor's assessment. Individual results will vary and not all patients will experience the same postoperative activity level or outcomes.
- Please be aware that surgery and recovery protocol may vary for each individual and any questions pertaining to the surgical procedure or postoperative protocol should be discussed with your surgeon.
- Postoperatively and until healing is complete, fixation provided by this device should be considered as temporary and may not withstand weight bearing or other unsupported stress. The fixation provided by this device should be protected. The postoperative regimen prescribed by your physician should be strictly followed to avoid adverse stresses applied to the device.

Please call your doctor if:

- You experience loss of function/range of motion
- You develop a fever greater than 38° Celsius
- Drainage continues from the site of your incision
- Your surgical site becomes more swollen, tender, and painful, with increased difficulty performing your exercises

If you have difficulty breathing or develop severe pain or chest pain, call 000 or report immediately to your local emergency room.

Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure in consultant with your physician. Device removal should be followed by adequate postoperative management.

Precautions

Use of the device varies from patient to patient and may be impacted by multiple factors:

1. Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.
2. Prior to use, inspect the device to ensure it is not damaged.
3. After use, the device may be a potential biohazard/sharps hazards and should be handled in accordance with accepted medical practice and applicable local and national requirements.
4. In the rare event of device or implant breakage, fragments can be located visually. Fragments can be removed manually through the incision site.
5. In the event of unsuccessful implantation, the device(s) should only be retrieved under visual confirmation and if loose. Any attempt at retrieving devices entrapped in tissue or without visual confirmation of location may result in tissue damage or injury to the patient.
6. Attention: avoid anatomical hazards.

Life of the Device

These devices are long-term fixation devices intended to aid in the normal healing process. They are not intended to replace the normal body structures or bear the weight of the body in the presence of incomplete healing. If healing is delayed, or does not occur, the device may eventually break due to fatigue.

Warnings

1. This device is intended to be used by a trained medical professional.
2. These instructions are not meant to replace proper training in surgical technique or arthroscopy. It is the surgeon's responsibility to be familiar with the appropriate surgical techniques prior to use of this device.
3. Do not use excessive tension or overload the device, as either could lead to device pullout or damage/ breakage.
4. The postoperative regimen prescribed by the physician should be strictly followed to avoid adverse stress applied to the implant.
5. The device is sterile for single use - DO NOT RESTERILIZE.
6. Reprocessing the device may result in bio contamination, degraded performance or loss of function. The devices were not designed or validated to be cleaned, disinfected or sterilized by the user.
7. Do not use after the expiration date.
8. Store in a cool, dry place, away from moisture and direct sunlight.
9. The device should be accepted only if the factory packaging and labeling are intact. If tampering or damage exists, do not use the device and contact your local Arthrex representative.
10. In the event of unsuccessful implantation, the device(s) should only be retrieved under visual confirmation and if loose. Any attempt at retrieving devices entrapped in tissue or without visual confirmation of location may result in tissue damage or injury to the patient.

MRI Safety Information

MRI, or Magnetic Resonance Imaging, is an imaging technique utilizing strong magnetic field to produce detailed anatomical images. This section details the information that you should be aware when getting a MRI scan.

- **MRI Safe**: This device has not been evaluated for safety and compatibility in the magnetic resonance (MR) environment. This device has not been tested for heating, migration or image artifact in the MR environment. The safety of the device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury. If the implant is manufactured from a metallic material, surgeons can expect that MR artifacts will be present during routine MR imaging.

Implant Models

FiberStitch™ Implant

Product Description	Item Number
FiberStitch Implant, Curved w/ 2 Polyester Implants and 2-0 FiberWire® Suture	AR-**4570**
FiberStitch Implant, Straight w/ 2 Polyester Implants and 2-0 FiberWire Suture	AR-**4570S**
FiberStitch Implant, Reverse Curve w/ 2 Polyester Implants and 2-0 FiberWire Suture	AR-**4570R**
FiberStitch Implant, 24° Curve w/ 2 Polyester Implants and 2-0 FiberWire Suture	AR-**4570-24**

Contact Information

Any serious incident that occurs in relation to a device should be reported to the manufacturer and to the health authority where the incident occurred.

Region	Contact
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Australia Therapeutic Goods Administration (TGA)	www.tga.gov.au

The information contained in this patient leaflet is not medical advice and is not meant to be a substitute for the advice provided by a surgeon or other qualified medical professional on the use of these products. You should talk with your physician or health care provider for more information about your health condition, and whether Arthrex products might be appropriate for you. The surgeon who performs any surgical procedure is responsible for determining and using the appropriate techniques for surgical procedures on each individual patient. Arthrex recommends that surgeons be trained on the use of any particular product before using it in surgery. A surgeon must always rely on their professional medical judgment when deciding whether to use a particular product when treating a particular patient. A surgeon must always refer to the package insert, product label, and/or directions for use before using any Arthrex product. Products may not be available in all markets because product availability is subject to the regulatory approvals and medical practices in individual markets. Please contact Arthrex if you have questions about the availability of products in your area.

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