Soft Tissue Fixation Product Range

PEEK RCI™ Screw

Interference Screw

BI-ON™ Screw and Anchor

Interference Screw

MEER Screw

Interference Screw

Shoulder Suture Anchor

Suture Anchor

Instructions for Use 121-051-003 Rev. E Issue Date:10/2015

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Caution:

Carefully read all the instructions and be familiar with the surgical technique(s) prior to use of the system. This product must only be used by trained, qualified persons, aware of the directions for use.

U.S. Federal law restricts this device to sale, distribution and use by or on the order of a physcian.

1 General Instructions

The Signature Orthopaedics range of soft tissue fixation implants are intended to reattach soft tissue to bone and to allow for long term biological fixation.

Prior to undertaking the procedure, patients must be evaluated according to the indications and contraindications of the particular system, as well as the patient selection criteria included in this document. Patients must also be informed of the precautions and possible adverse effects of the procedure, and of appropriate postoperative recovery procedures.

The surgeon must be thoroughly knowledgeable not only in the medical and surgical aspects of the implants, but must also be aware of their mechanical limitations. The device is intended to hold the soft tissue temporarily to allow long term biological fixation to take place. The device is not intended to support in-vivo loading indefinitely.

Signature Orthopaedics implants and instruments should only be used with approved devices and accessories.

2 PEEK RCI Screw

The PEEK RCI is an interference screw for use in fixation of ligament, tendon or soft tissue to bone in the knee. The screw is manufactured from unreinforced PEEK. The screw has a rounded head, variable thread form, central cannulation, and proximal grooves. The screw is provided individually packaged sterile for single use only.

3 BI-ON Screw and Anchor

The BI-ON screw and anchor is a combination interference screw and anchor for use in fixation of ligament, tendon or soft tissue to bone in the shoulder. The screw and anchor are used in combination to secure the graft. They are both manufactured from unreinforced PEEK. The screw is cannulated and the anchor is grooved. The screw and anchor are provided separately packaged, both sterile and intended for single use only.

4 Shoulder Suture Anchor

The Shoulder Suture Anchor is intended for use in fixation of ligament, tendon or soft tissue to bone in the shoulder. The Shoulder Suture Anchor secures the graft by anchoring the suture in place. The screw has a self tapping tip and eyelet to secure the suture. The Shoulder Suture Anchor is manufactured from unreinforced PEEK. The Shoulder Suture Anchor is individually packaged sterile with the insertion instrument and suture. The Shoulder Suture Anchor, suture and instrument are intended for single use only.

The Shoulder Suture Anchor may be used with the Double Auto Needle or the Alien Portal. The Double Auto Needle is a suture needle manufactured from nitinol. The needle is used to pass suture through deep tissue during arthroscopic surgery. The Alien Portal is a silicon cannula placed in the incision to provide an access port during arthroscopic surgery. The Double Auto Needle and the Alien Portal are both provided sterile, and intended for single use.

5 MEER Screw

The MEER screw is an interference screw for use in fixation of ligament, tendon or soft tissue to bone. The screw is manufactured from unreinforced PEEK infused with HA. The screw has barbs as opposed to threads to allow the screw to be impacted into place, as opposed to screwed in. The screw is provided individually packaged sterile for single use only.

6 Indications

Components of the Signature Orthopaedics range of soft tissue fixation devices are intended to reattach ligament, tendon or soft tissue to bone. Specifically, the BI-ON Screw and Anchor and Shoulder Suture Anchor are indicated for use in the shoulder, including:

Shoulder

- Capsular stabilization
  - Bankart Repair
  - Anterior shoulder instability
  - SLAP lesion repairs
  - Capsular shift or capsulolabral reconstructions
- Acromioclavicular separation repairs
- Deltoid repairs
- Rotator cuff tear repairs
- Biceps tenodesis

Additionally, the PEEK RCI Screw is indicated for use in the knee, including:

Knee

- ACL repairs
- PCL repairs
- Extra-capsular repairs
  - Medical collateral ligament
  - Lateral collateral ligament
  - Posterior oblique ligament
- Patellar realignment and tendon repairs
  - Vastus medialis obliquous advancement
- Illiotibial band tenodesis

7 Contraindications

Components of the Signature Orthopaedics range of soft tissue fixation devices are contraindicated for:

- Infection.
- Patient conditions including blood supply limitations, and insufficient quantity or quality of bone or soft tissue.
- Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.
- Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to implantation of the device.

8 Warnings and Precautions

1) U.S Federal law restricts this device to sale by or on the order of a physician.
2) It is the surgeon's responsibility to be familiar with the appropriate surgical techniques prior to use of this device. These instructions must be read in their entirety before use of the device.
3) Devices are supplied sterile and intended for single use only. Resterilization and re-use of the device is strictly prohibited. Resterilization of the device may alter device material properties including reducing mechanical properties and/or biocompatibility. Re-use of devices may result in cross-contamination between patients and decreased mechanical performance. Do not use the device if its packaging is damaged. Explanted devices are to be treated as biological hazards and disposed of immediately.
4) Adequately instruct the patient. Postoperative care is important. The patient's ability and willingness to follow instructions is one of the most important aspects of successful fracture management. Patients affected with senility, mental illness, alcoholism, and drug abuse may be at a higher risk of device or procedure failure. These patients may ignore instructions and activity restrictions. The patient is to be made aware and warned of general surgical risks, possible adverse effects, and to follow the instructions of the treating physician. The patient is to be advised of the need for regular postoperative follow-up examinations as long as the device remains implanted.
5) Correct handling of implants is extremely important. Do not modify implants. Do not notch or bend implants. Notches or scratches put in the implant during the course of surgery may contribute to breakage.
6) Prior to use, inspect the device to ensure it is not damaged. Do not use a damaged device.
7) Correct selection of the implant is extremely important. The potential for success in soft tissue to bone fixation is increased by the selection of the proper type of implant. While proper selection can help minimize risks, neither the device nor grafts, when used, are designed to withstand the unsupported stress of full weight bearing, load bearing or excessive activity.
8) Prosthetic components from different manufacturers must not be combined. All devices should only be used according to the package directions in conjunction with the specified surgical technique and instructions for use. Additional warnings and precautions may be included in component literature
9) Careful attention should be paid to asepsis and avoidance of anatomical hazards.
10) Inadequate fixation at the time of surgery can increase the risk of loosening and migration of the device or tissue supported by the device. Sufficient bone quantity and quality are important to adequate fixation and success of the procedure. Bone quality must be assessed at the time of surgery. Adequate fixation in diseased bone may be more difficult. Patients with poor quality bone, such as osteoporotic bone, are at greater risk of device loosening and procedure failure.
11) Do not attempt to implant this device within cartilage epiphyseal growth plates or nonosseous tissue.
12) The implants can loosen or be damaged and the graft can fail when subjected to increased loading associated with nonunion or delayed union. If healing is delayed, or does not occur, the implant or the procedure may fail. Loads produced by weight bearing and activity levels may dictate the longevity of the implant.
13) The use of appropriate immobilization and postoperative management is indicated as part of the treatment until healing has occurred.

9 Adverse Reactions

Components of the Signature Orthopaedics soft tissue fixation product range may have the following adverse reactions:

- Mild inflammatory reaction
- Foreign body reaction
- Infection
- Allergic reaction

10 Preoperative Planning

A thorough clinical evaluation of the patient must occur prior to undertaking surgery. Radiological scans must be taken to allow pre-operative templating and to allow assessment of the bony anatomy for possible deformities. The potential for satisfactory fixation is increased by the selection of the proper size, shape, and design of the implant.

At the time of the operation, the corresponding implantation instruments in addition to a complete set of implants must be available. It is important to determine pre-operatively whether the patient is allergic to any of the implant materials.

11 Postoperative Care and Mobilization

Instructions to the patient to reduce stress on the implants are an important part of the attempt to avoid the occurrence of clinical problems that may accompany fixation failure.

12 Patient Information

In addition to the contraindications for use, precautions and possible adverse effects, it is critical that the patient is aware that activity increases the risk of device or graft failure. The likelihood of clinical success is increased by appropriate postoperative care and the patient's ability and willingness to adhere to the surgeon's recommendations.

13 Packaging and Labeling

Components should only be used if the factory packaging and labeling are intact. If the sterile barrier has been broken, return the component to Signature Orthopaedics.

14 Sterilization and Resterilization

Implants are supplied sterile and have been double sterile packaged. The method of sterilization is noted on the package label. Dispose of the implant if the packaging is damaged. Resterilization of the implants is strictly prohibited, as it may alter the mechanical integrity of the device.

Unless specifically labeled sterile, instruments are supplied non-sterile and must be sterilized prior to use. The instrument included with the Shoulder Suture Anchor is not supplied sterile and is not reusable.

A complete guide for reprocessing reusable instruments may be provided upon request. As a guideline, the following sterilization method is recommended:

Method: Steam Autoclave

Cycle: Pre-vacuum

Temperature: 132°C (270° F)

Exposure time: 4 minutes

Drying time: 30 minutes

Note: Drying time is subject to variation depending on machine load.

15 Cleaning

Devices are supplied sterile and intended for single use only. Dispose of the implant if the packaging is damaged. Cleaning of the implants is not recommended.

Re-usable instruments are delivered non-sterile. The instrument included with the Shoulder Suture Anchor is not reusable. A complete guide for reprocessing reusable instruments may be provided upon request. As a guideline, the following cleaning method is recommended:

Manual Cleaning

Instruments are to be cleaned immediately after use with warm water and a mild detergent. Instruments consisting of multiple components must be disassembled prior to cleaning. After cleaning, the parts should be rinsed thoroughly with de-ionized water and dried.

Cleaning before Sterilization

Instruments may be cleaned using a broad spectrum bactericide and fungicide agent in accordance with the instructions of the manufacturer of the agent.

Caution:

Do not clean instruments with products containing Sodium Hypochlorite (NaOCl) and Sodium Hydroxide (NaOH).

Corrosive products or abrasive instruments should not be used.

Instruments should be thoroughly inspected to ensure that they are in good condition and operating order.

16 Storage and Handling

Implants and instruments are to be stored in dry, clean surroundings at room temperature, in their original packaging or sterilization tray respectively.

17 Limited Warranty / Liability

Signature Orthopaedics Europe Ltd. products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

Signature Orthopaedics Europe Ltd. shall not be liable for any incidental or consequential loss, damage, or expense, directly, or indirectly arising from the use of this product. Signature Orthopaedics Europe Ltd. neither assumes nor authorizes any other person to assume for it any other or additional liability or responsibility in connection with this product. Signature Orthopaedics Europe Ltd. intends that these instruments should be used only by physicians having received appropriate training in orthopaedic surgical techniques.

18 Manufacturer Contact Information

If more than 2 years have elapsed between the date of issue/revision of this document, and the date of patient consultation, contact the appropriate Signature Orthopaedics location for current information.

For further information or questions pertaining to sales and service, please contact your local sales representative or the appropriate Signature Orthopaedics location as listed below:

Signature Orthopaedics Europe Ltd

88 Harcourt Street.,

Dublin 2, Ireland

Tel: +353 1 6190632

Fax: +353 1 6915500

Signature Orthopaedics USA LLC

46 Chagrin Plaza, #118

Chagrin Falls, Ohio 44022

USA

Tel: 661 349 8502

Fax: 440 543 2174

Signature Orthopaedics Australia Pty Ltd

7 Sirius Road

Lane Cove NSW 2066

Sydney, Australia

Tel +61 2 9428 5181

Fax +61 2 8456 6065