Instructions for Use 121-051-003 Rev. M

Persons, aware of the directions for use. Carefully read all the instructions and be familiar with the surgical technique(s)

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 Bio-Composite Screw

The Bio-Composite Screw is an interference screw for use in fixation of ligament, tendon or soft tissue to bone in the knee. The screw is manufactured from PEEK/Hydroxyapatite composite. 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.

4 Signaloc Screw

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

5 Cardinal Screw

The Cardinal Screw is an interference screw for use in fixation of ligament, tendon or soft tissue to bone in the knee. The screw is manufactured from Titanium alloy. The screw has a constant taper, constant thread form, and central cannulation. The screw is provided individually packaged sterile for single use only.

6 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.

7 BI-ON Bio-Screw and Bio-Staple

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

8 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 eyeplet 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 Allen 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 Allen Portal is a silicon cannula placed in the incision to provide an access port during arthroscopic surgery. The Double Auto Needle and the Allen Portal are both provided sterile, and intended for single use.

9 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 bars 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.

10 Christmas Anchor

The Christmas anchor is intended for use in fixation of ligament, tendon or soft tissue to bone in the hip. The screw is manufactured from Titanium alloy. The screw has a self-tapping tip and eyeplet to secure the suture. The Christmas anchor is individually packaged sterile with a caddy to hold the anchor, suture and needle. The Christmas anchor, suture and needle are intended for single use only.

11 Vector Knotted

The Vector Knotted Suture Anchor is intended for use in fixation of ligament, tendon or soft tissue to bone in the shoulder. The Vector Knotted Suture Anchor secures the tissue by anchoring the suture in place. The anchor has a forked tip to capture the suture and offset barbs to prevent pullout. The Vector Knotted Suture Anchor is manufactured from unreinforced PEEK. The Vector Knotted 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.

12 PEEKay Anchor

The PEEKay Anchor is intended for use in fixation of ligament, tendon or soft tissue to bone in the shoulder. The PEEKay Anchor secures the tissue by anchoring the suture in place. The anchor has a forked tip to capture the suture and offset barbs to prevent pullout. The PEEKay Anchor is manufactured from unreinforced PEEK. The PEEKay Anchor is individually packaged sterile with the insertion instrument and suture. The Shoulder Suture Anchor, suture and instrument are intended for single use only.

13 ATOK Anchor

The ATOK (Arthroscopic Transosseous Knotless) anchor is intended for use in fixation of ligament, tendon or soft tissue to bone in the shoulder. The ATOK Anchor secures the tissue by anchoring the suture in place using a transosseous technique. The anchor has two components, a washer component which interfaces with the bone, and a ridge locking plug to secure the suture. The ATOK Anchor is manufactured from unreinforced PEEK. The ATOK Anchor is individually packaged sterile. The ATOK Anchor is intended for single use only.

14 EZ Flip

The EZ Flip ligament fixation system is intended for use in fixation of ligaments, tendons or soft tissue to bone in the knee. The EZ Flip system assists in ligament reconstruction by securing the looped end of the soft tissue. The system has three components; the plate which is manufactured from unreinforced PEEK, the loop which is manufactured from UHMWPE and the suture. The EZ Flip is provided individually packaged sterile for single use only.

15 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, BI-ON Bio-screw and Bio-anchor, Vector Knotted, PEEKay Anchor, ATOK 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
- Deltoïd repairs
- Rotator cuff tear repairs
- Biceps tenodesis

The Christmas anchor is indicated for use in the hip, specifically:

Hip
16 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.

17 Warnings and Precautions
22 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 mechanical integrity and quality are important to adequate fixation and success of the procedure. Bone and non-osseous tissue.

18 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

19 Preoperative Planning
A thorough clinical evaluation of the patient must occur prior to undertaking surgery. Radiographic 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 set of implants must be available. It is important to determine pre-operatively whether the patient is allergic to any of the implant materials.

20 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.

21 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.

22 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.

23 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 sterilized and is not reusable.

A complete guide for reprocessing reusable instruments may be provided upon request. As a guideline, the following cleaning 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.

24 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.

25 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.

26 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.

27 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:

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