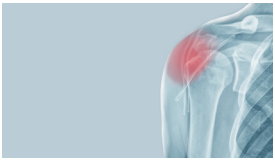
# PatientInfo

Soft Tissue Fixation

Signature Orthopaedics



**Soft Tissue Fixation**

This brochure offers a brief overview of soft tissue fixation, and the devices offered by Signature Orthopaedics. This information is for educational purposes only and is not intended to replace the expert guidance of your physician.

## When do you need soft tissue fixation ?

Your surgeon will evaluate your situation carefully if you are experiencing pain or poor range of motion in your shoulder, hip, and knee as a result of orthopaedic injuries. Your surgeon will carefully make decision regarding which implant is most appropriate for you and may determine which reconstruction and fixation type is the best method of treatment when other non-surgical treatments are ineffective. Soft tissue injuries occur when there is trauma or overuse occurs to muscles, tendons or ligaments. As a result, soft tissue fixation may be indicated for the following:

**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
-

**Knee:**

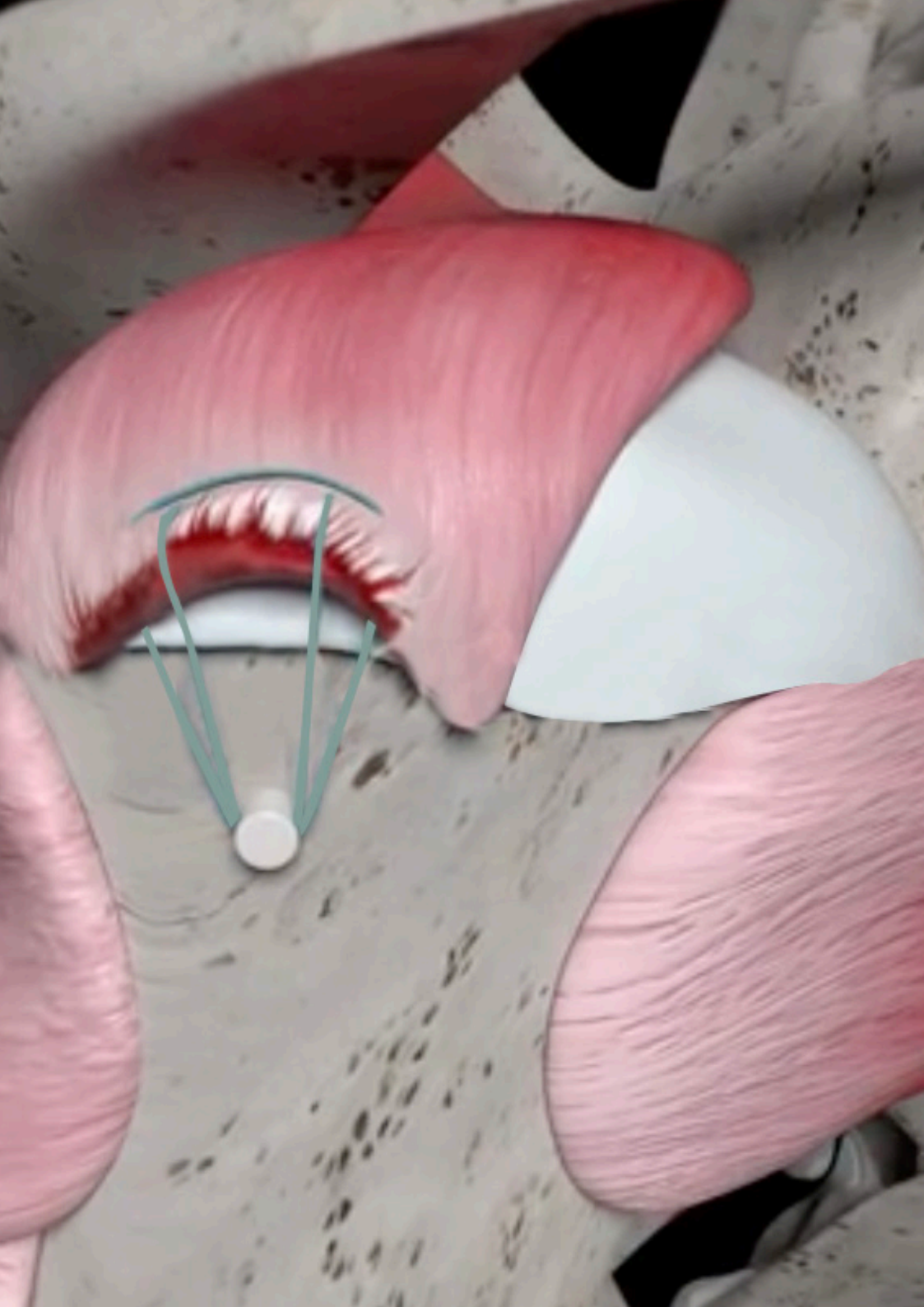
- ACL repairs
- PCL repairs
- Extra-capsular repairs
- Medical collateral ligament
- Lateral collateral ligament
- Posterior oblique ligament
- Patellar realignment and tendon repairs
- Vastus medialis obliquous advancement
- Illiotibial band tenodesis

**Hip:**

- Capsular repairs

*For more details on possible adverse effects and risks, please refer to the eIFU.*

Instructions for Use
Consult this Website
SignatureOrtho.com.au/eIFU

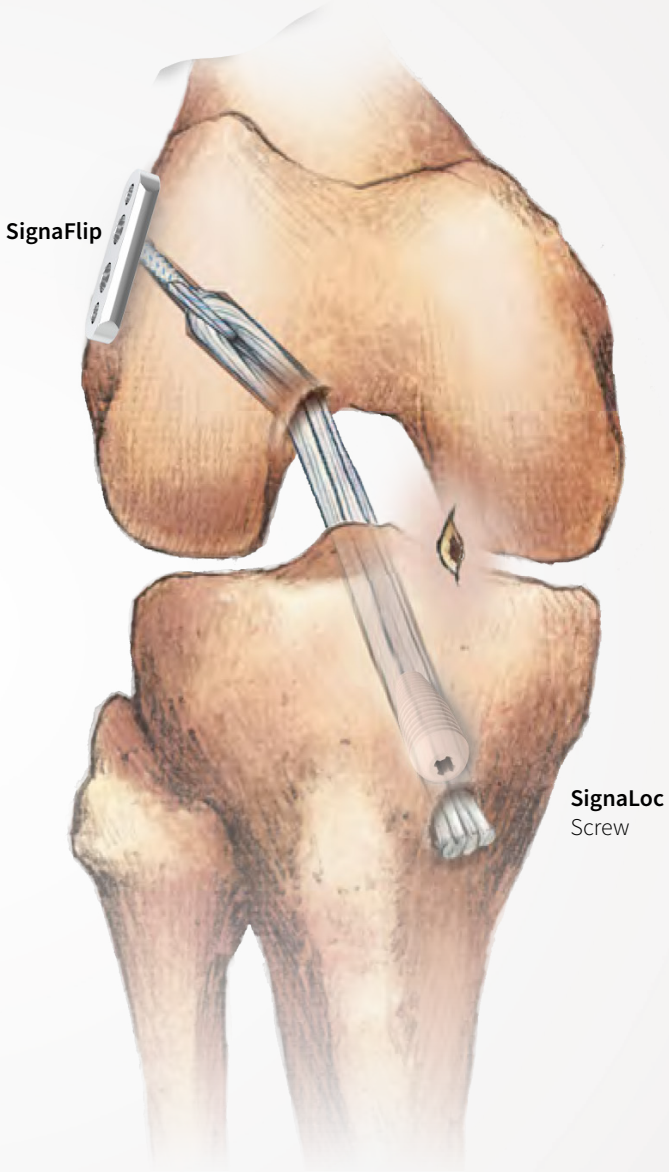


**Soft Tissue Fixation**

There are various fixation methods your surgeon can use. To list a few, there is the transosseous sutures, fixation with interference screws, staples, and etc..

## What is soft tissue fixation ?

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. Many factors influence the strength of a soft-tissue-to-bone fixation construct including tissue quality, implant strength, contact area and pressure, and tensioning. Each fixation technique differs in terms of biologic integration, biomechanical stability, and failure mechanism. Fixation methods may or may not require an implant, such as interference screws, staples, pins, or suture anchors. Your surgeon will determine the optimal method of soft-tissue fixation for successful repair or reconstruction.


SignaFlip
SignaLoc
Screw

**Soft Tissue Fixation**

As with any major operation, soft tissue fixation surgeries have possible complications. Every possible effort is made by the medical team to prevent complications but this cannot be accomplished without your participation.

# Adverse events and risks

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

*For more details on possible adverse effects and risks, please refer to the eIFU.*

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# When to visit the doctor?

**You should phone your physician anytime you have questions regarding your condition, care and activity level.**

Report any changes with your incisions, such as an increase in swelling, redness or drainage that worsens during your recovery. Call your physician if you experience persistent pain not relieved by pain medication, have side effects from medication or persistent swelling not relieved with ice or rest.

**Soft Tissue Fixation**

The lifetime of the Signature Orthopaedics devices are indefinite, when used in accordance with the Instructions For Use, as the prosthesis is intended to remain implanted for your lifetime.

## How long will my implants last ?

The subject devices are intended to remain implanted for indefinite long term use. The subject devices are designed to promote biological fixation of the graft with the bony tunnel. Biological fixation typically occurs in 3-12 months. Following biological fixation, the screw is subject to no loading and may be left implanted, at the surgeon's discretion.

**Soft Tissue Fixation**

Signature Orthopaedics offers a range of products applicable for various situations and anatomies, as determined by your physician. These are all available in a variety of sizes to accommodate different body sizes and shapes.

## Which implant is right for me ?

Although implant surgery is extremely successful in most cases, some patients will still experience pain and stiffness. Your physician will evaluate your particular situation carefully before making any decision regarding which implant is most appropriate for and discuss all complication and risks with you prior to surgery.

The selection of an implant of the correct size, shape and type of fixation is extremely important to maximise the potential for a successful, long term, outcome for the you.

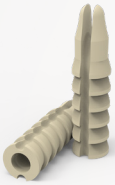
**Your doctor will evaluate your particular situation carefully before making any decision regarding which implant is most appropriate for you.**

### Shoulder Suture Anchor

The Shoulder Anchor is available in 5 variants and consists of a PEEK (ASTM F2026) fully threaded screw pre-loaded with UHMWPE suture(s) and assembled onto a single use driver for knotted use. The screw contains an eyelet to retain the suture(s). Variants include the standard turbine, mini-incision and osteoporotic anchors.

### BI-ON Bio-Screw

The BI-ON bio-screw and bio-staple are a set of PEEK/HA composite and HA coated (ISO 13779) PEEK interference screws. The staple is interference fit and the screw is cannulated and fully threaded, and work in combination to secure the soft tissue.



### Vector Knotted Screw

The Vector Knotted anchor is a barbed interference fit PEEK knotted anchor. The anchor features a series of barbs to enhance pullout strength and a cleft feature at the distal tip to capture and retain the sutures.

### ATOK Anchor

The ATOK anchor is a knotless anchor consisting of a PEEK washer and locking plug which work in tandem to secure the suture holding down the soft tissue.

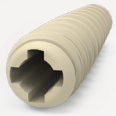
### Bondi Suture Anchor

The Bondi Suture Anchor is intended for use in fixation of ligament, tendon or soft tissue to bone in the shoulder. The Bondi Suture Anchor secures the graft by anchoring the suture in place. The Bondi Suture Anchor is manufactured from reinforced PEEK. The Bondi Suture Anchor is individually packaged sterile with the insertion instrument and suture. The Bondi Suture Anchor, suture and instrument are intended for single use only.

### Fresh Water Anchor

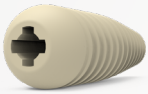
The Fresh Water Anchor is available in two sizes and manufactured from Titanium alloy. The Fresh Water anchor comes pre-loaded with #2 sutures.

**Peek RCI**



**Bio-Composite Screw**

**SignaLoc Screw**



**Cardinal Screw**

**SignaFlip**

The PEEK RCI screw, Bio-Composite screw, Signaloc screw, and Cardinal screw are interference screws which provide compression of the graft or tendon to the bony wall for biological fixation of the ligament, tendon or soft tissue to bone in the knee.

All screws feature an internal cannulation to accept a guide wire and all have the same drive feature.

The PEEK RCI, Bio-Composite and Signaloc screws have an external variable thread along the length of the tapered shape and a rounded head.

The Cardinal screw has a constant taper and a constant thread form.

The screw is provided individually packaged sterile for single use only.

The PEEK RCI screw is manufactured from unreinforced PEEK. The Bio-Composite Screw and the Signaloc Screw are manufactured from a PEEK/Hydroxyapatite composite.

The Cardinal Screw is manufactured from Titanium alloy.

Signature Orthopaedics' SignaFlip is a titanium alloy and a non-absorbable surgical poly suture

**Soft Tissue Fixation**

After successful surgery, your surgeon will evaluate your range of motion and your ability to use the muscle around your joint.

## Will I Return To Everyday Activites?

The decision on your post-operative activity level is dependent on your surgeon's recommendations and guidelines as well as your compliance with recommended post-operative therapy.

## CONTACT US

### How To Report Adverse Events

Any serious incident that occurs in relation to the device should be reported to your physician and the manufacturer, **Signature Orthopaedics**, by contacting the healthcare provider or emailing ***info@signatureortho.com.au*** ***info@signatureortho.eu***

If within Australia, you may also report an adverse event to the Therapeutic Goods Administration (TGA). More information regarding adverse events and how to report can be found at ***https://www.tga.gov.au/reporting-adverse-events***

Signature ORTHOPAEDICS

This leaflet is intended for use in Europe and Australia.
For the latest version of this leaflet,
please refer to ***www.signatureortho.com.au/patientinfo***

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