Patient Information Leaflet for Soft Tissue Anchor Implant

This leaflet has information about your implant. It does not contain all the information and if you have any questions, talk to your healthcare team. All implants have risks and benefits. Follow your healthcare team's advice even if it differs from what is in this leaflet. Please read this leaflet carefully and keep it in a safe place so you may refer to it in the future if needed.

The name and number of your soft tissue reattachment implant can be found on your implant card. If a healthcare professional asks about your implant, please show them your implant card.

The list of products that are covered by this leaflet can be found at the end of the leaflet.

Implant Description

The implant is used for soft tissue injuries of the knee, shoulder or elbow to reattach soft tissue such as ligaments or tendons to bone. Reattachment of soft tissue to bone aims to alleviate pain and improve limb function to allow you to resume many daily activities that may have been limited due to pain, weakness or restricted range of motion. It consists of an anchor that is implanted into bone that is used to hold the soft tissue to the bone after surgery.

Your doctor will choose the appropriate implant to meet your needs. As with any medical treatment, individual results may vary.

Implant Material

Your medical device may be constructed from the following: Tricalcium-Phosphate, Poly L-Lactic Acid, polyetheretherketone (PEEK), polypropylene, or Titanium alloy.

Information for Safe Use

You should have received a set of instructions from your doctor. These instructions may include exercises, therapies, and any limitations on your activities. It is very important that you follow your doctor's instructions. Your doctor will provide instructions about how to recover and restart activities. Make sure you attend all appointments. Healing takes time and your doctor will provide information on what to expect. Not following your doctor's advice may result in complications and the need for additional operations.

Images of your implant are often needed after your operation. X-rays and/or CT scans of your implant will not damage your implant or increase your risk of issues. If you are asked to go for an MRI scan, please show your implant card to the doctor and MRI technician. The MRI scan may interact with your implant and may cause issues if your technician is unaware of your implant. This will allow them to manage your MRI scan safely.

Possible Side Effects / Risks

Your doctor will provide information about the side effects of your operation. All operations have risks. The risk of a serious issue is low. There is a risk that you may require additional operations or treatments for several reasons. Please talk to your doctor if you have concerns.

Possible risks may include:

- Allergic reaction
- Infection
- Inflammation
- Foreign body reactions

These risks may require additional operations or treatments. This list does not include all risks. Your doctor can further explain the risks of your operation.

Expected Implant Lifetime and Follow Up

Having a soft tissue repair is a significant operation. While most people have a good result and an active recovery, there are potential surgical/medical risks and recovery takes time. Things such as your anatomy (your size and shape), medical condition, lifestyle (for example, weight and activity level) and surgery affect the result.

Your implant is designed to remain in your body. Implant lifetime is the time from implantation of your implant to when part (or all) of your implant is removed from your body or absorbed by the body. Your implant lifetime may be longer or shorter than the average. It is not possible to tell if you will have issues which may require additional operations. The lifetime for your implant depends on your specific medical needs. Your surgeon has access to data for your implant and will be able to provide more information based on your specific needs. Make sure you attend all your medical appointments.

Reporting Adverse Effects

If you wish to report any adverse effects you believe are a result of your soft tissue reattachment implant, please speak with your medical team or report the information to Johnson & Johnson Medical Product Safety Department at productsafetyjjmanz@its.jnj.com or the Therapeutic Goods Administration at https://www.tga.gov.au

For access to this leaflet, please visit: https://www.jnjmedicaldevices.com/en-AU/patient-information-leaflets

Sponsor

Johnson & Johnson Medical Pty Ltd t/a DePuy Synthes

1-5 Khartoum Rd, North Ryde, NSW 2113

Tel: 1300 562 711

List of Products

Absolute
BIO-INTRAFIX
Intrafix
Latarjet
Milagro
Profile