TRX Orthopaedics Limited

Patient Information Leaflet for OrthoPure® XT Ligament Reconstruction Implant

This leaflet has information about your implant. This leaflet does not contain all the information about your implant. If you have any questions, please talk to your doctor. All implants have risks and benefits. Always follow the advice of your doctor, even if it differs from what is in this leaflet.

Please read this leaflet carefully. Keep this leaflet in a safe place so you may refer to it in the future if needed.

The details of your implant can be found on your implant card. If a healthcare professional asks about your implant, please show them your implant card.

Implant Description

The OrthoPure® XT implant is intended to be used by an orthopedic surgeon. OrthoPure® XT is intended to treat patients who have suffered ligament injury in the knee joint, and who require ligament reconstruction surgery. The OrthoPure® XT implant is used to replace damaged knee ligaments to restore the function and stability of your knee joint.

The implant works with the tissues and bone in and around your knee. Over time, the implant will be replaced by your own tissue.

Your doctor will choose the implant size that best meets your medical needs.

Device Size	Catalogue Number
5	2405XTS
6	2406XTS
8	2408XTD
10	2410XTT

Implant Material

Your implant is made from animal tissue, specifically pig tendon. The implant contains pig collagen (approximately 32 %) and water (approximately 68 %).

Your implant is processed and sterilised to make sure it is safe.

TRX Orthopaedics Limited

Information for Safe Use

You should have received instructions from your doctor regarding exercises, therapies, and any limitations on your activities. It is very important that you follow these instructions about how to recover and restart activities. Make sure you attend all your appointments. Healing takes time and your doctor will give you information on what to expect. Not following your doctor's advice may result in problems and the need for further treatment.

Imaging for medical treatment, for example X-rays or MRI scans, will not damage or interact with your implant. If you are concerned, please ask your doctor.

Possible side effects or 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 need further operations or treatments for a variety of reasons. Please talk to your doctor if you have concerns about your treatment.

Possible side effects or risks may include:

- Graft rupture/failure
- Residual laxity and symptoms of instability

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

Contact your doctor if you think you are experiencing side effects related to the implant. This leaflet is not intended to replace a consultation with your doctor if needed.

Expected implant lifetime and follow-up

Your implant is designed to be permanent and remain in your body.

Having knee ligament replacement is a significant operation. Healing takes time and your doctor will give you information on what to expect. Most people have a good result, but results vary, and you may have complications. Factors such as your anatomy (your size and shape), medical condition, lifestyle (for example, weight and activity level) and surgery may affect the outcome.

Implant lifetime is the time from when the implant is put into your body to when the implant is either removed from your body or it is fully replaced by your own tissue. The expected lifetime of your implant in the body could be up to 60 years. The actual lifetime of your implant may be longer or shorter than expected. It is not possible to tell if you will have issues which may require further treatment.

Make sure you attend all your medical appointments. If you have questions, please speak to your doctor.

TRX Orthopaedics
Limited

Reporting Adverse Effects

If you wish to report any adverse effects you believe are a result of your implant, please speak with your doctor.

Any serious incidents that you believe are related to the implant should be reported to the manufacturer and to the Therapeutic Goods Administration as follows:

Manufacturer:

TRx Orthopedics, Unit 3 Phoenix Court, Lotherton Way, Garforth, Leeds, LS25 2GY, UK
customerservices@tissueregenix.com

Therapeutic Goods Administration:

https://www.tga.gov.au/

For access to the most up to date information for your implant, please visit:
https://www.tissueregenix.com/orthopaedics/orthopure-xt/information-for-patients/

To obtain a paper copy of this leaflet, please contact: enquiries@tissueregenix.com