

# Cartiva® Implant Surgery

## Patient Information Leaflet

### Introduction

This leaflet will explain what will happen when you come to the hospital for an operation to have a Cartiva® implant inserted into your toe joint.

### Why do I need this surgery?

You have been diagnosed with osteoarthritis in the joint at the base of your big toe. This joint is called the first metatarsophalangeal joint (MTPJ).

Osteoarthritis is a condition that results in thinning and wear of the cartilage within your joint. It is a progressive condition, so it does get worse over time. In the first MTPJ, arthritis causes the joint to become increasingly stiff and painful, often affecting all types of activity. When the pain becomes severe and has a significant impact on your daily activities despite all other measures, surgery is usually an option to relieve pain.

Until now the gold standard treatment is a joint fusion (1<sup>st</sup> MTPJ). If your toe has already become very stiff then it is likely that fusion surgery would be the best option. However, in those with arthritis and a good range of movement, fusion surgery is not always well tolerated as although pain is well treated the sudden loss of movement is a big change.

Cartiva® is a new implant that is intended to reduce pain and improve function in patients with osteoarthritis in the first MTPJ, whilst maintaining its remaining range of movement.

### What is a Cartiva® implant?

Cartiva® is a new synthetic cartilage implant designed to replace the damaged cartilage surface. It is made from polyvinyl alcohol (PVA), a material that mimics the properties of natural cartilage. It is similar to the material used in contact lens. It has been used in a number of medical device applications for more than 20 years. However its use in the first MTPJ is a relatively new concept.

Arthritis of 1<sup>st</sup> MTPJ



Cartiva® implant in position at 1<sup>st</sup> MTPJ

### What evidence is there that it works?

The Motion study showed good outcomes at 2 years in a multi-centre study that compared the Cartiva® implant to fusion surgery. Outcomes at 5 years for 27 patients demonstrated preservation of 10-30 degrees natural dorsiflexion (toe lifted off floor) and pain and sports scoring results remain improved. There were no x-ray concerns regarding failure of the implant. There is a small chance of needing to have the fusion surgery due to ongoing pain. Pain can take a long time to settle after a Cartiva®, sometimes over a year.

Further longer term results/outcomes are not yet available, therefore we do not yet know how long the implants can last. It is important you appreciate this before going ahead with surgery.

### **What if my pain does not get better?**

Whilst the majority of people experience a significant reduction in pain from this procedure, we cannot guarantee full pain relief and some patients have ongoing symptoms. The Studies suggest that 4-10% have ongoing symptoms that require further surgery. No surgery due to pain is recommended until a minimum of 1 year as the pain can settle over time. The Cartiva® implant does not adversely affect the outcome of any future fusion surgery.

### **What does surgery involve?**

The procedure is performed as day surgery in the Treatment Centre. Your surgeon will remind you of the surgical process and possible complications and will confirm your consent form taken previously in clinic. The surgery is performed under general anaesthetic and the anaesthetist will discuss this with you prior to surgery.

The operation will take about 45 minutes and is performed using a tourniquet around your thigh or ankle. After the operation you will be taken back to the ward and given a drink and something to eat. You will be advised on painkillers and once ready you will be discharged home. You will be given a post-operative shoe to wear. You must be driven home and have a responsible adult caring for you for 24 hours for your own safety. If you do not have anyone who can care for you, an overnight stay in hospital is required.

You will be advised of your follow-up appointment date, either on the day of discharge or by letter in the post.

### **What are the possible risks and complications?**

#### **General complications of foot surgery**

- **Pain.** There will be post-operative pain. For most people the pain passes after 24-48 hours and is tolerable with regular painkillers (following dosage recommendations).
- **Swelling.** This is a normal outcome of any operation. The extent of post-operative swelling varies and cannot be predicted. In some people the swelling reduces within a matter of weeks and in others could take many months to over a year. Application of an ice pack greatly reduces the swelling.
- **Infection.** There is a small risk of infection with all surgery. This would be treated with antibiotics. If you experience redness and discharge from the wound, contact the Treatment Centre on 01270 277922/23 Monday to Friday 7.00am to 9.00pm or contact your GP. Out of these hours contact NHS 111 Service by calling 111.
- **Deep Vein Thrombosis (DVT).** Also known as Venous Thromboembolism (VTE), this is a rare complication of foot surgery. There is also an increased risk if you take the contraceptive pill, HRT or smoke. If you have had a DVT in the past, please tell your surgeon. If you are thought to be at increased risk you will have an injection to thin your blood on the day of surgery. This might need to be repeated for up to 7 days following surgery.
- **Complex Regional Pain Syndrome (CRPS).** This is a rare but difficult complication. This is an abnormal response of the nervous system to surgery but can happen after simple trauma. This can lead to a variety of painful sensations in the foot, which require medical and pain relieving techniques.
- **Scarring.** As a result of your surgery you will have a scar on your foot. To begin with the scar will be raised, red and sensitive but with time it will usually settle.

## Specific complications of Cartiva® implant surgery

- **Joint stiffness.** This is fairly common in the early stages and usually improves with time.
- **Implant subsidence.** Rarely your bone doesn't support the implant properly and it can sink into the bone leading to recurrent pain. If this happens and is severe, then you can undergo revision surgery.
- **Wear.** The implant will wear out eventually. Currently no issues have been found with debris as the prosthesis wears. Longer term studies will help us with this after the 5 year stage.
- **Allergic reaction.** The potential for your body to react to this substance is very low indeed. Rare cases of tissue reaction have occurred and this can be treated by implant removal.

## How will I feel afterwards?

Although long-acting local anaesthetic, administered during the procedure, should control most of the pain for about 8 to 10 hours, you can expect some pain or discomfort after the operation. Painkillers will be discussed with you on the day of surgery and can be prescribed for you to take home if required.

## Recovering from surgery

### 0-14 days

You should aim to be moving around taking weight through the post-operative shoe for a maximum of 20 minutes in each hour. The rest of the time your foot should be elevated. You do not need to wear the shoe unless moving. We advise you to stay at home, do not drive or get your foot wet until you have been seen in the post op clinic and the wound has been treated.

### At 14 days

At the first post-operative appointment you will have a wound review. You will be advised to gradually increase your activity and gently exercise your big toe. Apply ice compresses to reduce remaining swelling.

### At 6 weeks

At the second post-operative visit the foot gradually returns to normal and the swelling reduces. You may continue applying ice compresses to the foot several times each day to reduce swelling.

### At 12 weeks

You will have been walking much more normally at this stage. Continue regular ice packs to reduce any remaining swelling. Gradually, you will recover strength, flexibility and mobility and should be experiencing the full benefit of surgery.

### Long term follow-up

As this is a new implant you will continue to have regular follow-up appointments. These will be at 26 weeks, 1 year, 2 years, then yearly until 5 years.

This information is available in audio, Braille, large print and other languages. To request a copy, please ask a member of staff.

This information has been reviewed by the Readers' Panel.

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