PATIENT INFORMATION

CARTIVA®

Synthetic Cartilage Implant

THE DIFFERENCE IS MOVING.™

CARTIVA®

THIS BROCHURE IS WRITTEN TO HELP YOU MAKE AN INFORMED DECISION ABOUT YOUR SURGERY.

Please read this entire brochure carefully. Keep this brochure. You may want to read it again. If you have additional questions, talk to your doctor. Only your doctor can determine the types of treatment that may be appropriate for you.

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GLOSSARY

Arthrodesis – Joint is fused with plates or screws.

Arthritis – Swelling (inflammation) of one or more of your joints. This can cause pain and stiffness that can worsen with age.

Articular Cartilage – A smooth, slippery, white tissue that covers the ends of bones at joints. Healthy cartilage in our joints makes it easier to move. It allows the bones to glide over each other with very little resistance. Articular cartilage can be damaged by injury or normal wear and tear.

Cheilectomy – A surgery that involves shaving bone from both the joint surfaces of your big toe and removal of the diseased portion of the metatarsal head.

Hallux Valgus – hammer toe that is bending of one or both joints of the second, third, fourth, or fifth (little) toes.

Hemi-arthroplasty – A surgery that implants a device to serve as the new surface of the first metatarsophalangeal head.

Joint – The location where bones connect and bend.

Metatarsal Head – The surface of the metatarsal bone in the big joint of the big toe.

Metatarsophalangeal Joint ("MTP joint") – The joint where your big toe begins. This joint joins the metatarsal bone and the middle bone of the big toe (proximal phalanx).

Total Joint Replacement – A surgery that implants devices to replace both sides of the MTP joint.

Osteoarthritis ("OA") – A type of arthritis that occurs when flexible tissue at the ends of bones (cartilage) wears down. OA can cause pain, stiffness and swelling. OA is a disease that can limit motion over time.

WHAT IS THE CARTIVA® SCI?

The Cartiva® Synthetic Cartilage Implant (Cartiva SCI) is a man-made (synthetic) implant that is made of a soft plastic-like substance (polyvinyl alcohol) and salt water (saline). These materials are combined and molded into a solid, slippery and durable implant. Figure 1 shows a picture of the Cartiva SCI. The implant replaces the damaged cartilage surface of the big toe.

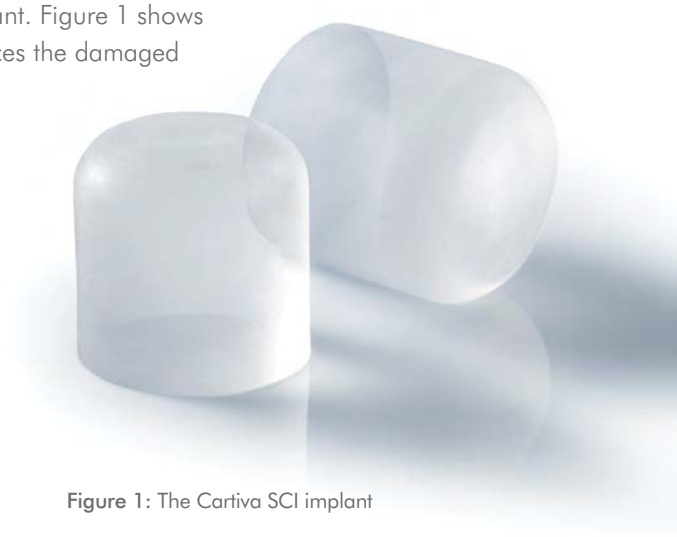


Figure 1: The Cartiva SCI implant

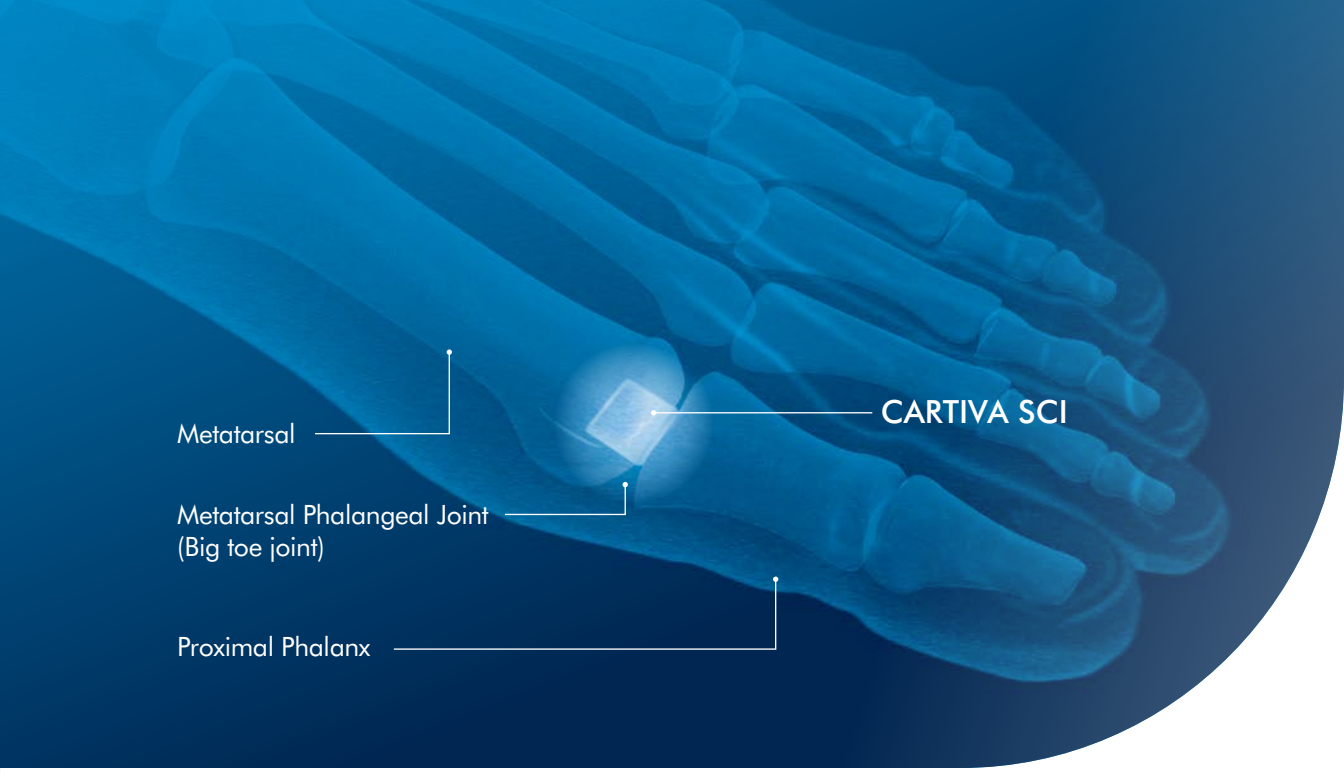


Figure 2: Metatarsophalangeal Joint (MTP joint) with the Cartiva SCI shown implanted

WHAT IS THE CARTIVA® SCI USED TO TREAT?

The Cartiva SCI is intended to treat painful arthritis in the joint of the big toe (first metatarsophalangeal joint). This arthritis of the big toe, also known as osteoarthritis or "OA", involves the wearing down of the cartilage tissue located in the big toe joint. The worn down cartilage can cause pain.

HOW DOES THE CARTIVA® SCI TREAT OA OF THE BIG TOE?

Your doctor thinks that the Cartiva SCI may help you. The Cartiva SCI (Figure 1) is made to replace the damaged cartilage surface of the big toe. The implant is placed into the bone in your big toe (See Figure 2 for an image of the bones of the big toe). The Cartiva SCI provides a new smooth, slippery surface in the joint. As a result, the Cartiva SCI may help relieve the pain and stiffness in your big toe caused by the worn cartilage.

WHAT YOU NEED TO KNOW

WHO SHOULD NOT RECEIVE THE CARTIVA® SCI (CONTRAINDICATIONS)?

- Tell your doctor if you think you have an infection in your foot. An infection makes it risky to have the Cartiva SCI. You might need another surgery to remove it because infections near the implant are hard to treat. Your doctor should not implant this device in you if you have an infection. (It is not allowed for use in patients with infections).
- Tell your doctor if you think you have ever had any allergy to or reacted to any plastic or an implant. The Cartiva SCI is made from a plastic-like mixture (polyvinyl alcohol and saline). You could be allergic to it. An allergic reaction to the Cartiva SCI might mean you would need more surgery to remove it. Your doctor should not implant this device in you if you might be allergic to it. (It is not allowed for use in patients who are allergic to polyvinyl alcohol or saline.)
- Tell your doctor if you have a form of arthritis called gout that also causes small lumps (tophi) to form under the skin around your joints. The Cartiva SCI might not work in your joint with this kind of arthritis. Your doctor should not implant this device in you if you have gout with tophi.
- Tell your doctor if you have any of the following conditions that can hurt implant support.
  - You had cancer
  - You had a hip dislocation
  - You have brittle bone or bone that breaks easily
  - You have taken a steroid medication in the past
  - You had an organ transplant
  - You have taken a medication called an immunosuppressant in the past
  - You have a history of any growths (tumors) in your bones

These conditions might lead to changes in your bone that might make the Cartiva SCI device unable to work properly.

You should speak to your doctor to determine if the above conditions apply to you, or if other conditions may make the Cartiva SCI not right for you.

WHAT ARE PRECAUTIONS RELATED TO THE USE OF THE CARTIVA® SCI?

- Not all patients with first MTP osteoarthritis were studied. The following patients were not in the Cartiva study:
  - Patients with hammer toe (hallux valgus) more than mild
  - Patients needing a Cartiva device in more than one joint
  - Patients needing a Cartiva device in a joint other than the MTP joint

WHAT WARNINGS SHOULD I KNOW ABOUT WHEN THE CARTIVA SCI® IS USED?

- Tell your doctor if you are younger than 22 years old. The Cartiva SCI device was not studied in people younger than 22 years old. The effect of the Cartiva SCI device for these people is not known.
- Tell your doctor if you have very poor bone quality due to poor blood supply (osteonecrosis) of the first MTP joint. The Cartiva SCI device was not studied in people with poor blood supply of the first MTP joint. The effect of the Cartiva SCI device for these people is not known.
- Tell your doctor if you have a low grade (Grade 1 or 0) of osteoarthritis in your big toe. The Cartiva SCI device was not studied in people with low-grade osteoarthritis of the big toe. The effect of the Cartiva SCI device for these people is not known.

HOW HAVE WE TESTED THE CARTIVA SCI® IN CLINICAL TRIALS?

- A controlled clinical study tested the Cartiva SCI. The study happened in hospitals in Canada and the United Kingdom. Patients had OA of the first MTP joint, similar to you. Study patients received the Cartiva SCI or a fusion of their first MTP joint. 202 patients were treated in this study. 152 patients received the Cartiva SCI implant. 50 patients had fusion surgery. Patients were seen over a two-year period from surgery including a visit two years after surgery. Of the Cartiva patients, 151 patients of the 152 were available for the two year visit and 47 of the 50 fusion patients were available at two years. The study results were reported to the U.S. Food and Drug Administration (FDA).
- The patients with the Cartiva SCI implant saw similar outcomes to the patients with the fusion treatment. In the clinical study, 89 out of every 100 Cartiva SCI patients had significant pain relief at two years after treatment. 98 out of every 100 Cartiva SCI patients maintained or improved their function at two years after treatment.
- 74 of every 100 Cartiva SCI patients maintained or improved their amount of motion at two years after treatment. People with a fusion surgery were unable to keep their motion. This motion in the Cartiva SCI patients did not cause better function in day-to-day activities. The Cartiva SCI and fusion groups had similar improvements in function at two years.

HOW LONG CAN I EXPECT THE CARTIVA SCI® TO LAST?

The Cartiva SCI device is a long-term treatment for your big toe joint. There have been limited cases where the Cartiva SCI was removed because a patient still had pain in their big toe joint. In the study, 9 out of every 100 Cartiva SCI subjects had the device removed within 2 years after surgery. In these cases, the patient's joint was fused with plates or screws (arthrodesis). The use of the Cartiva SCI device did not limit the patient's options for a successful fusion.

RISKS

WHAT PROBLEMS HAPPENED FROM CARTIVA® SURGERY?

The Cartiva SCI device study followed 152 patients for 2 years after surgery.

The most common adverse events were:

RISKS RELATED TO SURGERY		
Hazard	Harm	Patients
Pain due to surgical procedure	Pain in your toe	29 of 152
Wound swelling, draining or delayed healing or scarring	Wound swelling	10 of 152
	Buildup of fluid (edema) of 152	3 of 152
	Delayed healing	1 of 152
	Scar	1 of 152
	Wound discharge	1 of 152
	Thickening of tissue that can cause pain or stiffness	1 of 152
Joint stiffness or hardening of your joint (induration)	Joint stiffness	2 of 152
	Hardening of your joint (induration)	1 of 152
Tendon swelling (inflammation)	Painful or swollen tendon	2 of 152
Damage to nearby nerves, arteries or veins	Nerve pain (burning or sharp pain sensation)	1 of 152
Infection	Collection of fluid in the skin surrounding your stitches	1 of 152
Numbness in toes	Sensation of weakness, numbness and/or pain in your toes	1 of 152
Changes in the way you walk (gait disturbance)	Pain in other joints	1 of 152
Blood clot formation in one or more of the deep veins in your body (deep vein thrombosis), collection of fluid in the lungs (pulmonary embolism), or blood clot (thrombosis) formation in other vessels	We did not see anyone harmed like this in our study of 152 patients, but this harm is possible.	—
Reactions to the drugs or anesthesia (the medicine they used to put you to sleep) used during and after surgery	We did not see anyone harmed like this in our study of 152 patients, but this harm is possible.	—
Heart attack	We did not see anyone harmed like this in our study of 152 patients, but this harm is possible.	—
Blood loss, blood vessel damage, swelling (inflammation) of the blood vessel in your leg (phlebitis) or a localized collection of blood outside the blood vessels (hematoma)	We did not see anyone harmed like this in our study of 152 patients, but this harm is possible.	—
Stroke	We did not see anyone harmed like this in our study of 152 patients, but this harm is possible.	—
Surgery at the wrong side or level	We did not see anyone harmed like this in our study of 152 patients, but this harm is possible.	—
Death	We did not see anyone harmed like this in our study of 152 patients, but this harm is possible.	—

RISKS RELATED TO IMPLANT

Hazard	Harm	Patients
Additional surgery to remove or replace the implant due to more pain	Device removal and fusion	14 of 152
	Device removal and replacement	1 of 152
	Fusion (no device removal)	1 of 152
Other operative procedures	Scar tissue break up	1 of 152
Pain and discomfort associated with the operative site or presence of implants	Implant site pain	1 of 152
	Medical device pain	6 of 152
Joint with excess motion (instability) or at an abnormal angle (malalignment)	Foot deformity	3 of 152
	Bunion	1 of 152
Swelling or escape of fluid in body cavity (effusion)	Implant site swelling	2 of 152
Fracture of part of your sesamoid or metatarsal bone	Toe or foot pain or treatment to repair the fracture	3 of 152
Progressive osteoarthritis or disease of the joint (arthropathy)	Gradual loss of cartilage which can cause pain or swelling (inflammation)	1 of 152
	Joint disease that may cause pain or impingement (loss of joint movement)	2 of 152
Changes to the foot bone	Fluid filled hole within your foot bone	1 of 152
	Painful bone spur growth	1 of 152
Implant may loosen, wear out, or break which may need another operation to remove the implant and may need another method of treatment	Device moved from correct place (migration) so device not in right place	1 of 152
Sensitivity or allergy to the implant material	We did not see anyone harmed like this in our study of 152 patients, but this harm is possible.	—
Bone loss	We did not see anyone harmed like this in our study of 152 patients, but this harm is possible.	—
Poor positioning of the implant	We did not see anyone harmed like this in our study of 152 patients, but this harm is possible.	—
Joint or bone irritation	We did not see anyone harmed like this in our study of 152 patients, but this harm is possible.	—
Damage to surrounding tissues	We did not see anyone harmed like this in our study of 152 patients, but this harm is possible.	—
Other unexpected reactions	We did not see anyone harmed like this in our study of 152 patients, but this harm is possible.	—

The information in these tables is based on the first 2 years after surgery. It is unknown what adverse events may develop after 2 years. It is also unknown how many subjects may develop them. In this study, we did not observe some adverse events we thought were possible. The harm possible from them and their frequencies are unknown based on this clinical trial. It is unknown whether they will happen and how often they will happen with greater use of this device.

Please speak to your doctor immediately if you are experiencing any of these complications or if you feel you are experiencing symptoms that seem beyond post-operative healing, if you are sick to your stomach, have a fever, redness or rash, itching, tenderness or swelling of the operative foot.

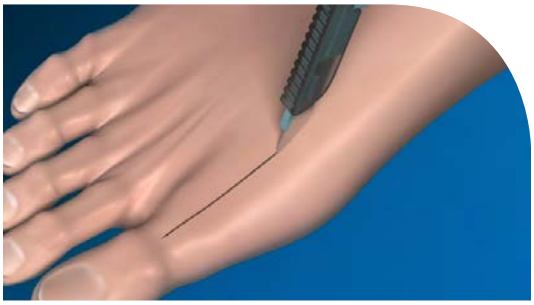
PROCEDURE

WHAT WILL HAPPEN BEFORE SURGERY?

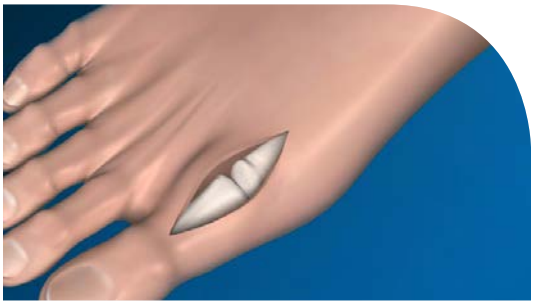
Your doctor will give you instructions prior to your surgery. You should follow these instructions the day before the operation. This surgery usually occurs without an overnight stay in the hospital. The procedure usually lasts about 25 minutes.

WHAT WILL HAPPEN DURING SURGERY?

The Cartiva SCI goes through a small cut in the top of your toe. You will be given drugs. The drugs will make you sleep during surgery. You will not feel the surgery.

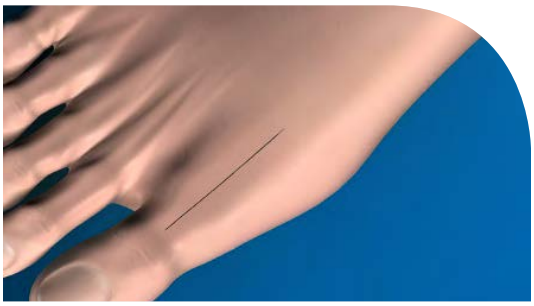


1: First, your doctor will make a small (about 2 inch) cut in the skin over the top of your big toe joint.



2: This will open the joint of your big toe. Then, the doctor will use special tools to remove bone to make a hole for the implant.

3: Your doctor will then place the Cartiva SCI into the hole. The Cartiva SCI implant provides a smooth, slippery, load-bearing surface.



4: The Cartiva SCI stays in place without the use of cement or glue. Then, your doctor will close the cut in your toe with stitches.

WHAT CAN I EXPECT AFTER SURGERY?

Ask your doctor about what will help you recover from surgery. It is important to follow your doctor's instructions carefully. You may begin putting weight on your toe as soon as you feel ready. You should begin exercises that move your joint immediately following surgery. You may need the help of a physical therapist to help you walk smoothly and without limping during your recovery. You should see your doctor to check on your progress after surgery.

WHEN SHOULD I CALL MY DOCTOR?

Ask your doctor to describe how you will feel after surgery. Some pain and discomfort is normal. The problems you had before surgery may not lessen right away. Talk to your doctor about when to call with problems after surgery.

You should call your doctor immediately if you have too much pain, are sick to your stomach and vomit, or have a fever, redness or rash, itching, tenderness, or swelling of the foot.

ARE THERE ALTERNATIVES TO USING THE CARTIVA® SCI?

Surgery will likely be recommended by your doctor if other non-operative methods have not been successful at reducing your big toe arthritis pain. You may wish to ask your doctor about any other possible treatments for your big toe arthritis pain.

Other surgical treatment options may include:

- **Cheilectomy:** A surgery that involves shaving bone from both the joint surfaces of your big toe and removal of the diseased portion of the metatarsal head.
- **Hemi-arthroplasty:** A surgery that replaces part of your joint with metal or plastic parts to serve as the new surface of the first metatarsophalangeal head.
- **Total Joint Replacement:** A surgery that replaces your joint with metal and plastic parts to replace both sides of the MTP joint.
- **Fusion (arthrodesis):** A surgery where the two sides of the MTP joint are cleared of cartilage. The two bones are held together with plates and/or screws so that the bones grow together. Fusion was studied and compared to the results for patients implanted with the Cartiva device, as discussed above.

Your doctor will have more information on each of these options and other possible treatments, as well as the benefits and risks for each of the treatment options.

WHERE DO I FIND OUT MORE INFORMATION ABOUT THE CARTIVA® SCI?

For additional information about the Cartiva SCI, visit our website at **www.cartiva.net** or information published on the US Food and Drug Administration's website at **www.fda.gov**.

TALK TO YOUR DOCTOR

This pamphlet is meant to give you useful information and knowledge about the Cartiva SCI implant. It is not intended to replace medical advice or instruction from your doctor.

Your doctor or physician is the only person responsible and qualified to appropriately diagnose and treat your health condition. Should you have any questions about the Cartiva SCI implant or its relevance to your course of treatment, please call your doctor.

CARTIVA®

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