

THE DIFFERENCE IS MOVING.™

CARTIVA® SYNTHETIC
CARTILAGE IMPLANT (SCI)
FOR BIG TOE ARTHRITIS

WHAT YOU NEED TO KNOW



CARTIVA®
Synthetic Cartilage Implant

WHAT IS BIG TOE ARTHRITIS?

THE BIG TOE JOINT HOLDS THE MAJORITY OF YOUR WEIGHT EVERY TIME YOU STEP.¹

Over time, that pressure can cause the cartilage in your joint to wear down, leading to painful arthritis and the inability to move your big toe. If you have been diagnosed with big toe arthritis, you are not alone.



1 IN 40
PEOPLE OVER AGE 50
ARE AFFECTED²

WHY IS TREATMENT IMPORTANT?

BIG TOE ARTHRITIS CAN CAUSE TENDERNESS, ACHINESS, AND PAIN.

These symptoms do not go away. They actually get worse over time as your cartilage continues to wear down. This can limit your big toe motion, impact how you walk, and make things you used to do even more challenging.

That's why early treatment, with surgery and CARTIVA® SCI, is important to help reduce pain and maintain current big toe motion, which can improve your long-term mobility.^{3,4,8}

HOW CARTIVA® SCI CAN HELP

Many people with big toe arthritis believe that their only treatment option for pain is fusion surgery. A procedure that involves fusing bones together, it eliminates movement of the big toe.

CARTIVA® SCI is different. It replaces damaged cartilage with an implant made of state-of-the-art synthetic material that acts like natural cartilage. This reduces pain and **preserves big toe motion⁷**, so you can stay active.³ CARTIVA® SCI can help you stay on your toes for all that life brings.



93%
PATIENT
SATISFACTION^{4,9}

ABOUT THE PROCEDURE

40 PERCENT FASTER THAN FUSION.

The surgical procedure that utilizes CARTIVA® SCI typically takes just 35 minutes—40% faster than fusion.⁵ It is performed in an outpatient setting, so no hospital stay is necessary. Although you'll need to wear a postoperative shoe, you may begin to put some weight on your big toe as soon as you feel ready.³ Fusion requires a cast and crutches.⁵

Taking time to recover properly is important to unlocking long-lasting pain reduction and improved mobility with CARTIVA® SCI^{4,6}

RESULTS WITH CARTIVA® SCI

You may feel significantly less pain as soon as 2 weeks after surgery, and significantly improved foot and ankle function as soon as 3 months after surgery.^{3,10} Plus, your condition may continue to improve over time:



93%
LESS PAIN
THROUGH 2 YEARS^{3,11}



97%
LESS PAIN REPORTED
AT ALMOST 6 YEARS^{4,12}



176%
MORE FOOT FUNCTION
AT ALMOST 6 YEARS^{4,13}



15%
OF PATIENTS HAD THEIR
IMPLANTS SAFELY REMOVED
AT ALMOST 6 YEARS^{17,18}

VISIT WWW.CARTIVA.NET/SAFETY
FOR IMPORTANT SAFETY INFORMATION AND
ADDITIONAL RISKS RELATED TO USE OF THE IMPLANT.

REASONS TO CHOOSE CARTIVA® SCI

Only your surgeon can determine if CARTIVA® SCI is right for you and your big toe arthritis pain. However, it's important to consider the following:

	CARTIVA® SCI	Fusion Surgery
Substantial pain relief ^{3,14}	●	●
Joint continues to move as intended ³	●	●
Big toe motion preserved ^{3,15}	●	●
No limitations in choice of shoe wear	●	●
Less restrictive recovery and rehabilitation ^{5,16}	●	●

CARTIVA® is not right for everyone and only your doctor can determine whether CARTIVA® is right for you. Speak to your doctor to see if CARTIVA® is right for you. Individual results and activity levels after surgery vary and depend on many factors including age, weight and prior activity level and your results and activity levels may not be the same as those referenced in this brochure. There are risks and recovery times associated with any surgery and there are certain individuals who should not undergo surgery. Only your doctor can tell you if CARTIVA® and the associated procedure are right for you and your unique circumstances. Please consult with your doctor for complete information regarding benefits, risks, anticipated implant duration and possible outcomes.

**SCHEDULE YOUR CARTIVA® SCI
IMPLANT TODAY!**

VISIT [CARTIVA.NET](http://WWW.CARTIVA.NET)
FOR SPECIFIC RECOVERY INFORMATION AND
ADDITIONAL IMPORTANT SAFETY INFORMATION,
OR ASK YOUR SURGEON FOR A CARTIVA® SCI
RECOVERY GUIDE.

INDICATIONS:

WHAT IS 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.

CONTRAINDICATIONS:

WHO SHOULD NOT GET THE CARTIVA® SCI?

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.

For more information and helpful videos,
visit [CARTIVA.net](https://www.cartiva.net)

1. Jacob HAC. Clin Biomech. 2001;16(9):783-792.
2. Gould N, Schneider W, Ashikaga T. Foot Ankle. 1980;1(1):8-10.
3. Baumhauer JF, Singh D, Glazebrook M, et al. Foot Ankle Int. 2016;37(5):457-469. Results for participants varied and your results may vary as well. Speak to your doctor to see if Cartiva is right for you.
4. Glazebrook M, Blundell CM, O'Dowd D, et al. Foot Ankle Int. 2019;40(4):374-383. Foot mobility measured using patient reported outcomes from the Foot and Ankle Ability Measure (FAAM) Sports score. Results for participants varied and your results may vary as well. Speak to your doctor to see if Cartiva is right for you.
5. Glazebrook MA, Younger ASE, Daniels TR, et al. Foot Ankle Surg. 2018; 24(5):440-447. Results for participants varied and your results may vary as well. Speak to your doctor to see if Cartiva is right for you.
6. Baumhauer JF, Daniels T, Glazebrook M. Orthop Clin North Am. 2019;50(1):109-118. Results for participants varied and your results may vary as well. Speak to your doctor to see if Cartiva is right for you.
7. In the CARTIVA clinical trial, a substantial and clinically meaningful reduction in pain using the Visual Analog Scale (VAS) median pain scores was reported by CARTIVA patients (n=106) at every follow-up visit through 5.8 years. Patients (n=106) maintained motion of the big toe demonstrating a median 25% improvement in dorsiflexion toe motion at 5.8 years.
8. In the CARTIVA clinical trial, a substantial and clinically meaningful reduction in pain using the Visual Analog Scale (VAS) median pain scores was reported by CARTIVA patients (n=106) at every follow-up visit through 5.8 years. Patients maintained motion of the big toe demonstrating a median 25% improvement in dorsiflexion toe motion at 5.8 years. Mobility measured using patient reported outcomes from the Foot and Ankle Ability Measure (FAAM) Sports score. A substantial and clinically meaningful improvement in median FAAM sports score was reported by CARTIVA patients (n=105) at 5.8 years.
9. When queried at 5.8 years, 93% of patients (n=106) indicated they would undergo the CARTIVA for big toe joint arthritis procedure again.
10. In the CARTIVA clinical trial, a substantial and clinically meaningful reduction in pain using the Visual Analog Scale (VAS) median pain scores was reported by CARTIVA patients (n=130) at the 2 week follow-up visit. A substantial and clinically meaningful improvement in median Foot and Ankle Ability Measure (FAAM) sports score was reported by CARTIVA patients (n=127) at the 3 month follow-up visit.
11. In the CARTIVA clinical trial, a substantial and clinically meaningful reduction in pain using the Visual Analog Scale (VAS) median pain scores was reported by CARTIVA patients (n=130) at the 2 year follow-up visit. CARTIVA patients demonstrated a 93% reduction in median pain from baseline out to 2 years.
12. In the CARTIVA clinical trial, a substantial and clinically meaningful reduction in pain using the Visual Analog Scale (VAS) median pain scores was reported by CARTIVA patients (n=106) at the 5.8 year follow-up visit. CARTIVA patients demonstrated a 97% reduction in median pain from baseline out to 5.8 years.
13. Function measured using patient reported outcomes from the Foot and Ankle Ability Measure (FAAM) Sports score. A substantial and clinically meaningful improvement in median FAAM sports score was reported by CARTIVA patients (n=105) at 5.8 years. CARTIVA patients demonstrated a 176% improvement in median FAAM sports scores from baseline out to 5.8 years.
14. In the CARTIVA clinical trial, a substantial and clinically meaningful reduction in pain using the Visual Analog Scale (VAS) median pain scores was reported by CARTIVA patients (n=106) at the 5.8 year follow-up visit. CARTIVA patients demonstrated a 97% reduction in median pain from baseline out to 5.8 years.
15. In the CARTIVA clinical trial, patients (n=106) maintained motion of the big toe demonstrating a median 25% improvement in dorsiflexion toe motion at 5.8 years.
16. CARTIVA patients are not required to wear a cast and are weight bearing immediately as tolerated following surgery. At the two week and six week follow up time points, CARTIVA patients (n=130) demonstrated clinically and statistically significantly higher FAAM sports, FAAM activities of daily living and SF-36 physical functioning subscores versus big toe joint fusion patients.
17. Data on file. Wright Medical Group N.V. Memphis, TN. In the CARTIVA clinical trial, at 24 months, 14/152 patients had undergone implant removal and conversion to arthrodesis. In years 2 to 5.8, 9/119 patients underwent implant removal and conversion to arthrodesis.
18. Glazebrook M, Baumhauer J, Davies MB. Revision of Implant to Great Toe Fusion: Did We "Burn a Bridge" With a Synthetic Implant Hemiarthroplasty? Foot & Ankle Orthopaedics. 2017 Sep 11;2(3):2473011417S000044.

