**Cartiva Synthetic Cartilage Implant (SCI)®**

**Frequently Asked Questions**

**What is Osteoarthritis (OA)?**

According to the Arthritis Foundation, osteoarthritis (OA) is the most common chronic condition of the joints. Sometimes called degenerative joint disease or “wear and tear” arthritis, it occurs when the cartilage or cushion between joints breaks down leading to pain, stiffness and swelling. Osteoarthritis is a progressive condition where motion becomes increasingly limited.

**Where does arthritis occur in the foot?**

The most common site of arthritis in the foot is in the big toe joint, clinically referred to as the metatarsophalangeal (MTP) joint, which is subjected to a great deal of stress, bending with each of the thousands of steps taken each day. Because arthritis is a progressive, chronic condition, it can make walking and even standing difficult and painful.

**How many people have arthritis of the big toe joint?**

One in 40 Americans over the age of 50 have arthritis of the big toe joint, also called hallux rigidus.

Hallux rigidus usually develops in adults between the ages of 30 and 60 years. Risk factors include family history, prior injury to the toe that damages the articular cartilage, and differences in foot anatomy that increase stress on the joint.

**Aside from the pain, what other issues does arthritis of the big toe joint, or hallux rigidus, cause?**

With limited motion due to arthritis, the other joints of the body need to compensate, further straining the rest of the foot and lower extremity. Over time, bone spurs form on top of the joint restricting motion in the big toe leading to increased pain and discomfort. As a result, functional and sporting activities are often restricted. Many patients experience limitations in shoewear, such as heels, cowboy boots, and ski boots.

**What are the symptoms of arthritis of the big toe?**

* Pain in the joint when active
* Increased discomfort during standing or walking
* Joint swelling and tenderness
* A bump, such as a bunion or callus, on the top of the foot

**How is arthritis of the big toe treated?**

When arthritis causes moderate to severe joint damage, most often fusion (arthrodesis) is performed. In a fusion procedure, the cartilage is removed, the bones are prepared, and the joint is fixed in a permanent position with a combination of screws and plates. Over 6-8 weeks, the bones grow together.   
  
While fusion is an effective treatment in reducing pain caused by arthritis, it permanently prevents movement of the joint. As a result, fusion patients may experience limitations in their daily activities and sports.

**When did Cartiva SCI become available to treat arthritis of the big toe joint?**

The U.S. Food and Drug Administration (FDA) granted Premarket Approval (PMA) to the Cartiva Synthetic Cartilage Implant (SCI)® in July 2016. Cartiva SCI is the first synthetic cartilage device approved by the FDA—and the first Premarket Approval (PMA)—of any device used to treat this condition. A Premarket Approval is the most stringent type of device marketing application required by the FDA.

Cartiva SCI has been approved for use outside the United States since 2002 and is available in Europe, Canada and Brazil. Over 4,000 implants have been used to date.

**How does the Cartiva SCI work?**

The Cartiva SCI implant replaces the damaged cartilage. The Cartiva SCI is implanted in a simple outpatient surgical procedure lasting approximately 35 minutes, where a surgeon exposes the joint by making a small 4-5cm incision. The damaged cartilage is removed and replaced with Cartiva, a biocompatible, biomedical polymer implant, providing a cartilage-like, smooth, load-bearing joint surface.

**What benefits does the Cartiva SCI offer over fusion?**

Level I clinical evidence from the MOTION study, a 236-patient, multi-center, prospective randomized study comparing Cartiva SCI to fusion—the largest study ever conducted for this clinical condition—shows:

* Cartiva SCI to be non-inferior to fusion in the treatment of OA of the first MTP when evaluating pain, function and safety
* Cartiva patients demonstrated clinical success of 80% for the composite primary endpoint (pain, function and safety) at 24 months compared to 79% success for the fusion arm
* Cartiva patients achieved a 93% reduction in median pain
* Cartiva patients demonstrated a 168% improvement in median function of sporting activities and 65% improvement in activities of daily living
* Cartiva patients experienced a 26% improvement in range of motion from baseline[[1]](#endnote-1)

Unlike a fusion procedure, Cartiva patients can begin weight bearing immediately as tolerated.

**What is Cartiva SCI made of?**

The implant is a biocompatible, biomedical polymer implant made from material that has been used in a number of medical device applications for more than 20 years. Cartiva SCI mimics the properties of articular cartilage.

**Who makes the Cartiva SCI?**

Cartiva SCI is manufactured, marketed and distributed by Cartiva, Inc. Based in Alpharetta, Ga., Cartiva, Inc., develops and markets innovative solutions for patients with cartilage damage and osteoarthritis.

**When will Cartiva SCI be available in the U.S.?**

The Company plans to make Cartiva SCI available across the country in the coming months. For information on where Cartiva is available please visit [www.cartiva.net](http://www.cartiva.net) or call (770) 754-3855.

1. FDA PMA #P150017 and Panel Executive Summary located at <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/OrthopaedicandRehabilitationDevicesPanel/UCM496456.pdf> [↑](#endnote-ref-1)