

THE DIFFERENCE IS MOVING.™

IMPORTANT SAFETY INFORMATION

INDICATIONS AND USAGE

The CARTIVA® Synthetic Cartilage Implant is intended for use in the treatment of patients with painful degenerative or post-traumatic arthritis (hallux limitus or hallux rigidus) in the first metatarsophalangeal joint with or without the presence of mild hallux valgus.

CONTRAINDICATIONS

The CARTIVA® SCI should not be implanted in subjects with the following conditions:

- Active infection of the foot
- Known allergy to polyvinyl alcohol
- Inadequate bone stock due to significant bone loss, avascular necrosis, and/or large osteochondral cyst (>1 cm) of the metatarsophalangeal joint
- Lesions of the first metatarsal head greater than 10 mm in size
- Diagnosis of gout with tophi
- Physical conditions that would tend to eliminate adequate implant support (e.g., insufficient quality or quantity of bone resulting from cancer, congenital dislocation, or osteoporosis), systemic and metabolic disorders leading to progressive deterioration of bone (e.g., cortisone therapies or immunosuppressive therapies), and/or tumors of the supporting bone structures

PRECAUTIONS

The safety and effectiveness of this device has not been established in subjects with the following conditions:

- Pediatric patients (< 22 years of age)
- Subjects with osteonecrosis of the first metatarsophalangeal joint
- Osteoarthritis involving the first metatarsophalangeal joint with grade 0 or 1 hallux rigidus per the Coughlin Scale¹

The safety and effectiveness of the CARTIVA® SCI device for treatment in the presence of hallux varus to any degree or hallux valgus >20° is unknown.

The safety and effectiveness of using more than one CARTIVA® SCI device per joint is unknown.

The safety and effectiveness of the CARTIVA® SCI device at anatomic locations other than the first metatarsophalangeal joint is unknown.

The CARTIVA® SCI device should only be used by experienced surgeons who have undergone training in the use of this device. A lack of adequate experience and/or training may lead to a higher incidence of adverse events.

CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at eifu.cartiva.net for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

A complete Summary of Safety and Effectiveness (SSED), surgical technique, and labeling information for the CARTIVA® Synthetic Cartilage Implant may be obtained at www.fda.gov by searching PMA number P150017.

1. Coughlin MJ, Shurnas PS. Hallux rigidus. Grading and long-term results of operative treatment. *American Journal of Bone Joint Surgery*. 85-A(11):2072-88. November 2003.

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Examine all instruments prior to surgery for wear or damage. Replace any worn or damaged instruments. Use aseptic technique when removing the CARTIVA® SCI device from the innermost packaging.

Carefully inspect the device and its packaging for any signs of damage, including damage to the sterile barrier. Do not use CARTIVA® SCI devices if the packaging is damaged or the implant shows signs of damage.

Use care when handling the CARTIVA® SCI device to ensure that it does not come in contact with objects that could damage the implant.

Damaged implants are no longer functionally reliable. The CARTIVA® SCI device should not be used with components or instruments from other manufacturers. CARTIVA® SCI device should not be re-used or re-implanted. Ensure proper alignment and placement of device components as misalignment may cause excessive wear and/or early failure of the device.

POTENTIAL ADVERSE EVENTS

Below is a list of the potential adverse effects (e.g., complications). In addition to the risks listed below, there is also the risk that surgery may not be effective in relieving symptoms, or may cause worsening of symptoms. Additional surgery may be required to correct some of the adverse effects.

1. Risks associated with foot surgical procedures include: infection, blood clots, blood loss, damage to adjacent nerves, arteries, or veins, anesthesia-related problems, allergic reaction, numbness in the toes, painful scars, pain when wearing shoes or walking, incomplete correction of the problem, recurrence of the deformity, heart attack, stroke, nerve damage, deep vein thrombosis (DVT), pulmonary embolus (PE), and death.
2. Risks associated with implantation of hemi-arthroplasty devices or CARTIVA® Synthetic Cartilage Implant include infection, inflammation, pain, swelling, effusion, joint irritation, fibrosis, joint instability, joint malalignment, periarticular cyst, bone cyst, bone loss, sesamoid bone(s) irritation, sesamoid bone(s) fracture, metatarsal bone fracture, osteonecrosis, avascular necrosis, implant fracture, implant loosening, implant dislocation, implant dislodgement, implant subsidence, revision or conversion to fusion, allergic reaction to polyvinyl alcohol (PVA), progressive osteoarthritis (OA), incorrect implant placement, and damage to adjacent or surrounding tissues.

For the specific adverse events that occurred in the clinical study of the CARTIVA® SCI device, please see the Safety Results in the CLINICAL STUDIES section of the IFU.