CARTIVA®

Synthetic Cartilage Implant

The First and Only **PMA Approved** Product for the Treatment of First MTP Joint Osteoarthritis

FOOT

First MTP Joint

THE DIFFERENCE IS MOVING.™

CARTIVA® – **PROVEN RESULTS** AT NEARLY 6 YEARS
CLINICAL OUTCOMES DATA

-97%

SUBSTANTIAL REDUCTION IN PAIN

A substantial and clinically meaningful reduction in pain using the Visual Analog Scale (VAS) was observed for CARTIVA® patients at 5.8 years. CARTIVA implant patients demonstrated a 97% median reduction in pain from baseline out to 5.8 years.[2]

+176%

SUBSTANTIAL FUNCTIONAL IMPROVEMENT

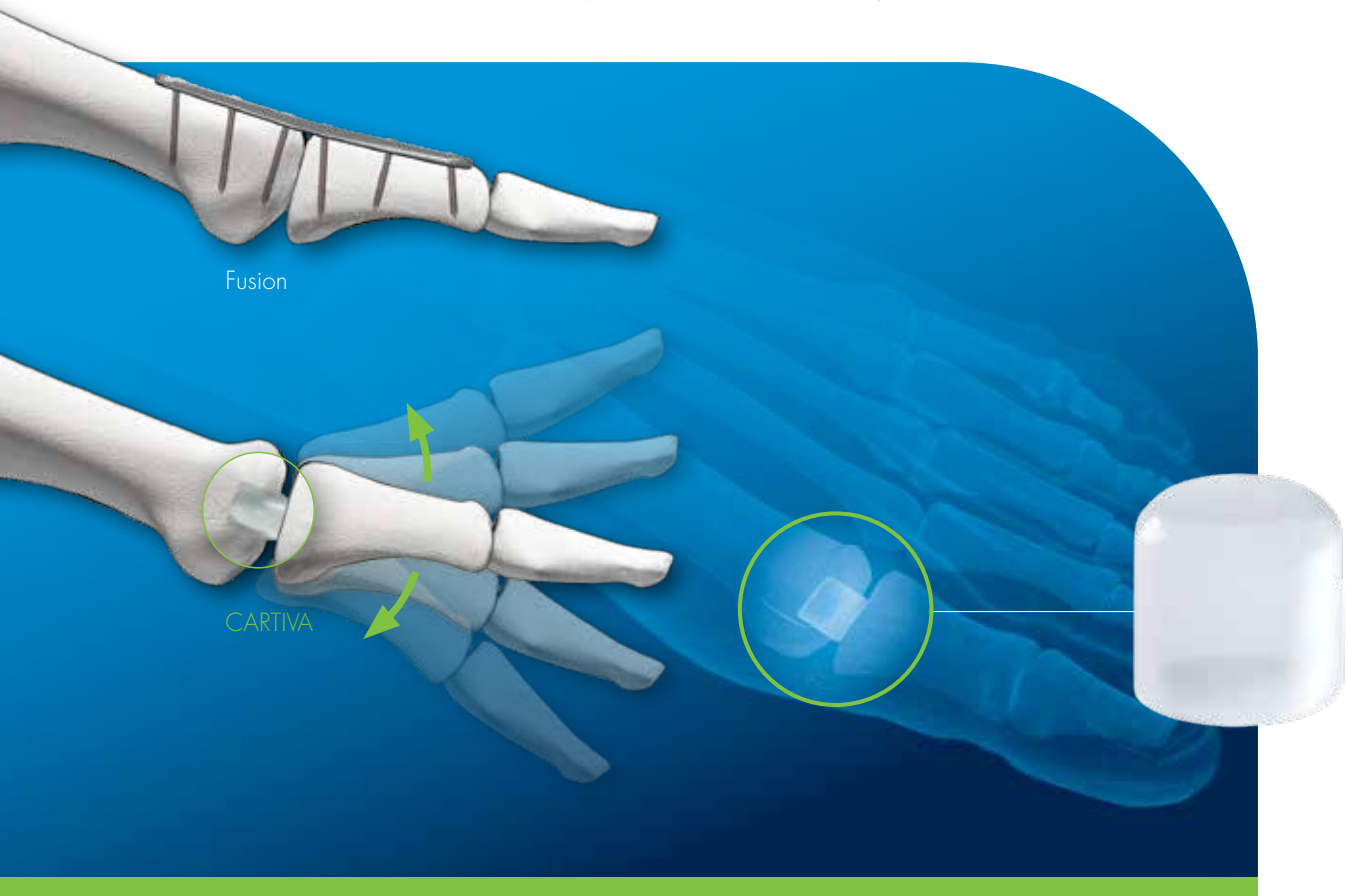
Functional activities were evaluated using the validated Foot and Ankle Mobility Measure (FAAM). A substantial and clinically meaningful improvement was observed in the median FAAM sports score at the 5.8 year follow-up with CARTIVA patients reporting a 176% median improvement in the sporting activities score.[2]

93%

PATIENT SATISFACTION

When queried at 5.8 years, 93% of patients indicated they would undergo the CARTIVA for first MTP joint osteoarthritis procedure again.[2]

Level 1 Clinical Evidence of safety and effectiveness for treatment of First MTP Joint Osteoarthritis, in the largest randomized study ever conducted for this condition.[1]



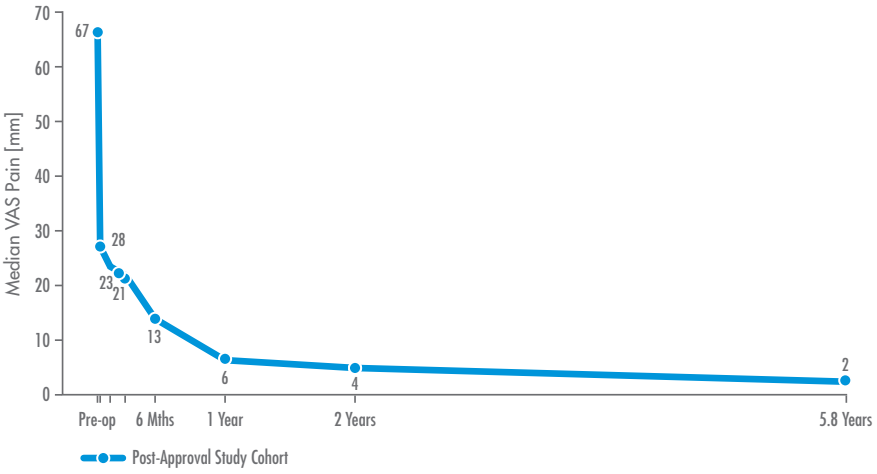
THE **FIRST & ONLY PMA** ALTERNATIVE TO FUSION
+ PROVEN LONGEVITY

Patients experience a **substantial reduction in pain** and **functional improvement** while maintaining joint motion.

5.8 YEARS

Substantial Pain Reduction[2]

N = 106

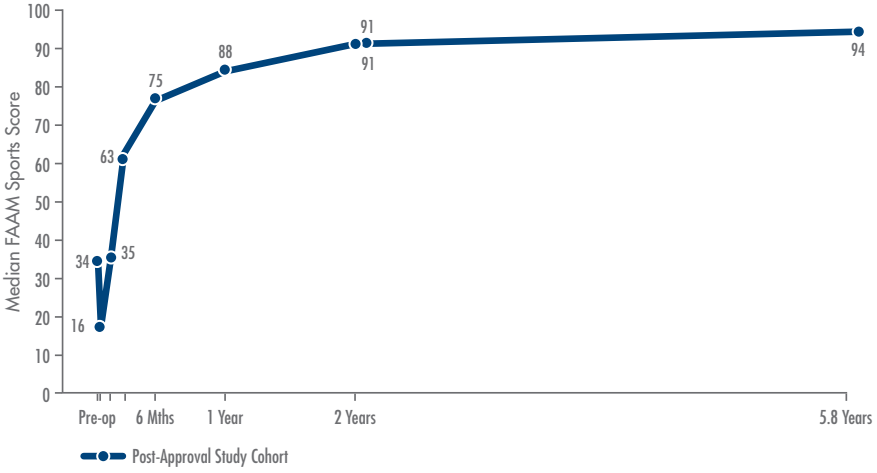


-97%

REDUCTION

Substantial Functional Improvement[2]

N = 105



+176%

IMPROVEMENT

FASTER THAN FUSION
FAST & SIMPLE SURGICAL PROCEDURE

CARTIVA® surgeries are **40%** (23 minutes) **faster** than fusion surgeries.[3]

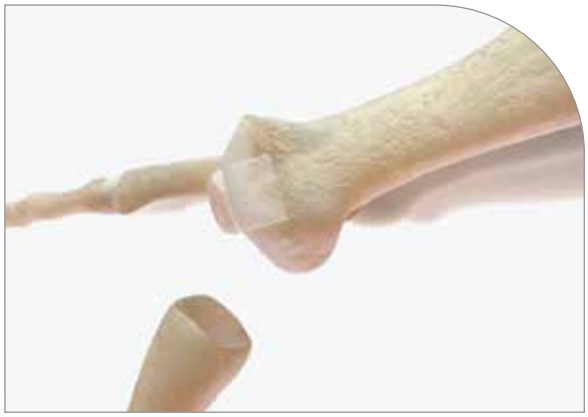
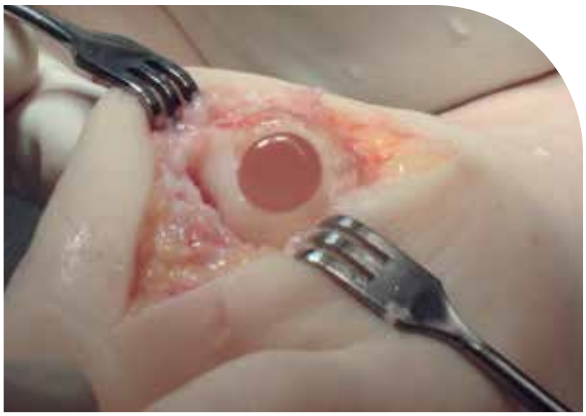


Illustration of the CARTIVA device implanted into the metatarsal head



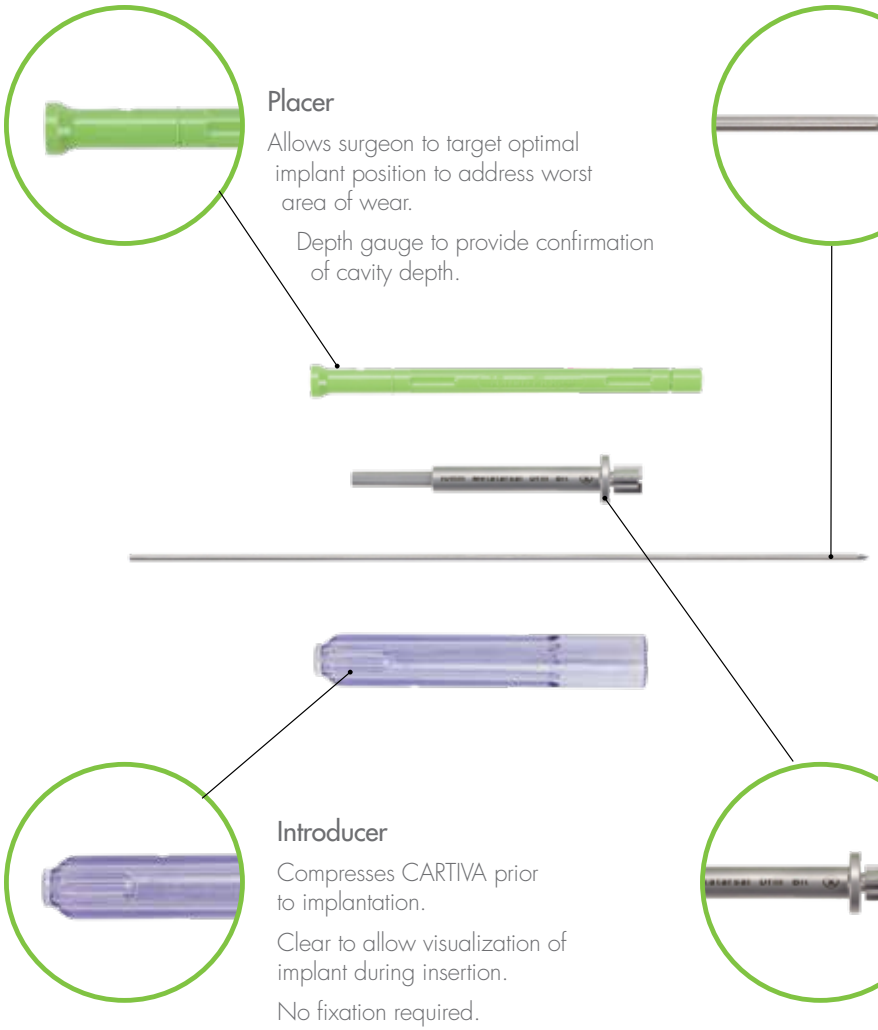
Damaged cartilage replaced with new CARTIVA implant bearing surface

SETTING A NEW STANDARD
FOR TREATING **HALLUX RIGIDUS**

- First new articular surface material **approved by FDA** in 17 years
- The only FDA approved **cartilage-like polymer**
- **Proven effective** in the largest, longest multi-center trial ever conducted for first MTP OA[1]
- Study data evaluated as **low risk of bias** in comprehensive published review[4]
- Awarded the **Roger A. Mann Award twice** (2015 & 2017), for the best clinical research in foot and ankle[1,5]

SINGLE-USE INSTRUMENTATION
IMPROVES FACILITY EFFICIENCY

CARTIVA's next generation instrumentation is a **compact, off-the-shelf set** that provides surgeons with new, sterile instrumentation for every single surgery. No post-op reprocessing saves costs and improves efficiencies for facilities.



Placer

Allows surgeon to target optimal implant position to address worst area of wear.

Depth gauge to provide confirmation of cavity depth.

Placement Guide Pin

2.0 mm non threaded.

Instrumentation

Specific to the size of the device (8 mm or 10 mm) being implanted.

Introducer

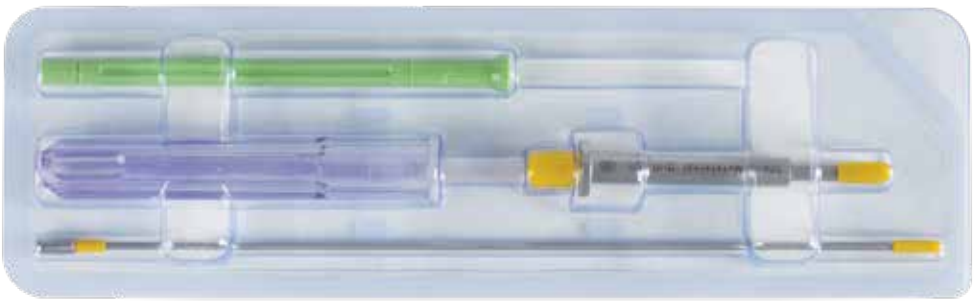
Compresses CARTIVA prior to implantation.

Clear to allow visualization of implant during insertion.

No fixation required.

Metatarsal Drill Bit

Stop to ensure proper height of press-fit implant.



Off-the-shelf sterile set minimizes the risk for contamination.

PATIENT BENEFITS
QUICKER RECOVERY

CARTIVA® SCI patients return to pre-operative activities faster than fusion patients.[3]

- No cast, full weight bearing immediately as tolerated, able to drive
- Range of motion exercises encouraged immediately

HYDROGEL THAT WORKS
LIKE NATURAL CARTILAGE

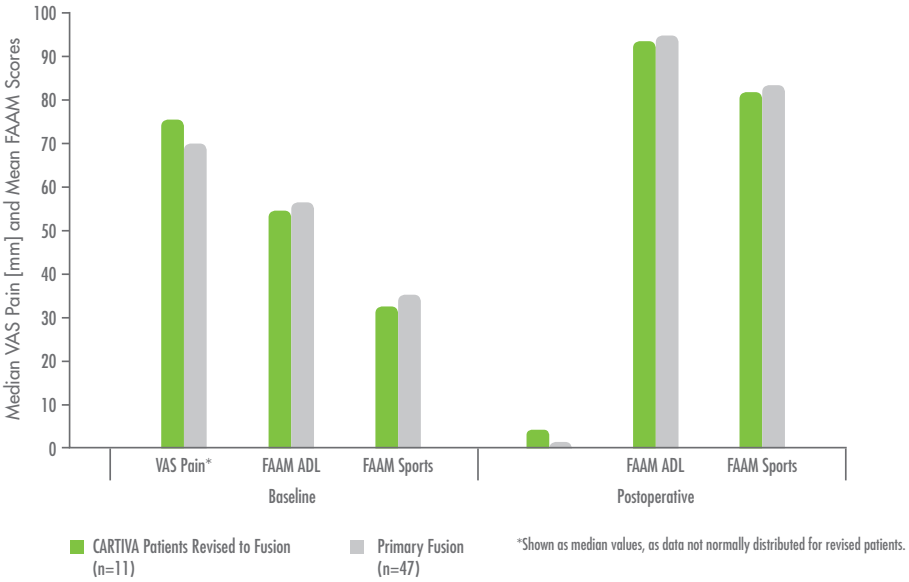
Mechanical and physical properties similar to native cartilage.

PROPERTY	ARTICULAR CARTILAGE[6,7]	CARTIVA
Water Content	60-80%	60%
Compressive Modulus	0.3 – 0.8 MPa	2.5-3.2 MPa
Coefficient of Friction	<0.01 – 0.05	0.04 – 0.07

FEATURES	BENEFITS
Synthetic	No risk of viral or bacterial transmission associated with human or animal derived materials
Biocompatible	Composed of saline and an organic polymer
Durable	Mechanical and physical properties similar to native cartilage capable of withstanding repetitive loading typical of MTP joint
Slippery	Low coefficient of friction aids joint articulation and mobility

BURNS NO BRIDGES

REVISED CARTIVA VS. PRIMARY FUSION: OUTCOME SCORES



CARTIVA SCI does not "burn a bridge" to excellent pain relief and successful functional outcomes, if a revision procedure is needed.[8]

EXTENSIVELY TESTED

BIOCOMPATIBILITY OF CARTIVA DEVICE		
TEST	**METHOD/MODEL**	**RESULT**
Cytotoxicity	L929 MEM Elution	Non-cytotoxic
Cytotoxicity	Direct Contact	Non-cytotoxic
Sensitization	Kligman Maximization	Non-sensitizer
Irritation/Intracutaneous	IC Injection	Negligible irritant
Acute Systemic Toxicity	Systemic Injection	Negative
Subchronic Toxicity	Femoral Condyle Implantation	Non-toxic
Chronic Toxicity	Femoral Condyle Implantation	Non-toxic
Genotoxicity	Ames Reverse Mutation	Non-mutagenic
Genotoxicity	Chromosomal Aberration Assay	Non-clastogenic
Genotoxicity	Rodent Bone Marrow Micronucleus	Non-clastogenic
Implantation	Bone Implantation In Femoral Condyle	Negative/no reaction
Pyrogenicity	Rabbit Pyrogen Test	Non-pyrogenic
BIOCOMPATIBILITY OF CARTIVA INSTRUMENTATION		
Cytotoxicity	L929 MEM Elution	Non-cytotoxic
Sensitization	Kligman Maximization	Non-sensitizer
Irritation/Intracutaneous	IC Injection	Negligible irritant

ANIMAL SAFETY STUDIES		
Animal Study 1 Year Goat	CARTIVA device implanted in load bearing region of medial femoral condyle in stifle of 8 mature goats; control defects in 4 goats At one year, knees evaluated via - High field strength MR imaging system for morphology and quantitative T2 and T1-rho parameters; - Histological processing - Biomechanical testing	- No evidence of local or systemic toxicity - No inflammatory reaction around implant or osteolytic bone loss - Non-significant change to opposing tibial-surface - No difference in presence of subarticular cysts with control - No device fragmentation or dislodgement - No particulate migration
Particulate Implant Study 6 month rabbit	- 5 million cycle wear debris quantified and characterized - Particulate replicated and injected via bolus in a quantity 9x - Test injections and control (saline) administered to 16 animals. At 3 and 6 months, histology and pathology per ISO standards	- No complications on injection - No test-article related adverse changes - No significant findings on clinical observation, gross pathology, histomorphometry, or histopathology of localized tissue - Systemic issues showed no microscopic changes related to the treatment - No wear debris or foreign body giant cells with injected material
FUNCTIONAL TESTING		
Fatigue Testing	Cycles: 5 million Test Surface: Stainless Steel Axial Load: 4 MPa	- Mechanical durability demonstrated after 5M continuous cycles at peak load of 4 MPa - Significant mass and height recovery upon unloading - The CARTIVA device demonstrated adequate strength to survive the repetitive, compressive loads that occur clinically in the 1st MTP.
Wear Testing	Cycles: 5 million Test Surface: Cartilage Simulated Axial Load: 4 MPa	- Resistance to wear demonstrated after 5M continuous cycles at simulated peak load of 4 MPa - 0.18% average mass loss (1.64 mg) - Worse case wear debris over 5 years of 2.88 mg or 0.31% - Volumetric wear rate of 1.50 mm3/yr that is considerably lower than UHMWPE (80 mm3/year)[9]
MATERIALS PROPERTIES		
Unconfined Compression	Loading of unconfined devices to achieve 10%, 20%, 30% and 40% strain to measure deformation resistance of the matrix and determine compatibility of the device with surrounding native tissue	**CARTIVA** / **Articular Cartilage** Compressive Modulus: 3.05±0.12 MPa / .31–.80[10] MPa Equilibrium Elastic Compressive Modulus: 2.68–3.34 MPa / 0.54[11] MPa
Confined Compression	Devices confined in compression fixture with 5%, 10%, 15%, 20% and 25% strain applied to assess matrix stiffness at equilibrium (ie when load-induced fluid flow has ceased).	Higher polymer content and presence of physical cross links in CARTIVA results in a mean aggregate modulus of 6.7±1.0 MPa where cartilage values range between 0.6 and 1.2 MPa.
Shear	Devices seated between test blocks that are moved apart perpendicularly until failure or 5 mm displacement; thereby, providing a baseline understanding of the simple shear properties of the material.	**CARTIVA** / **Articular Cartilage** Shear Moduli: 0.16–0.36 MPa / 0.45[12] MPa (0.22 –0.68 MPa) Fatigued devices exhibited no change in shear properties and resistance to mechanically induced degradation properties. All devices exhibited full 100% lateral shear strain without tearing or showing shear fracture.
Creep	4 MPa loading in confined compression fixture to elucidate structural changes since equilibrium swelling properties are sensitive to the nature and stability of the hydrogel crosslinks	- Biphasic creep - 4-5% mass loss
S-N Analysis	Devices loaded in a confined fixture to 8, 12, 18, and 24 MPa out to 5,000,000 cycles	- No catastrophic failure - Continuous 5M compression cycles - Extreme loads of 24 MPa (6 x peak load) - Even under significant stresses, no failures

IMPLANTS

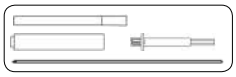
CAR-10-US
10 mm CARTIVA MTP Implant

CAR-08-US
8 mm CARTIVA MTP Implant

SINGLE-USE INSTRUMENTATION

MTK-10
10 mm Single-Use Instrumentation Set

MTK-08
8 mm Single-Use Instrumentation Set



For Customer Service Call: 877-336-4616

REUSABLE INSTRUMENTATION

DRILL BITS

MTD-10
10 mm Counterbore Drill Bit

MTD-08
8 mm Counterbore Drill Bit

GUIDE PINS

PNN-02
2 mm Guide Pin, Non-Threaded
(6 per pack)

INTRODUCERS

INT-10
10 mm Introducer

INT-08
8 mm Introducer

PLACERS

PLC-10
10 mm Placer

PLC-08
8 mm Placer

STERILIZATION TRAY

TRA-05-US
Sterilization Tray

BRIEF SUMMARY OF IMPORTANT PRODUCT INFORMATION

INDICATIONS

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, defined as a hallux valgus angle less than or equal to 20° (greater than 20° was an exclusion criteria in the clinical study).

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 immuno-suppressive 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 Scale[13]

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.

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 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.

CITATIONS:

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13. Coughlin MJ, Shurnas PS. *American Journal of Bone Joint Surgery.* 85-A(11):2072-88. November 2003.

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