

# CARTIVA®

Synthetic Cartilage Implant

The Only **PMA Approved** Product for  
the Treatment of 1st MTP Osteoarthritis

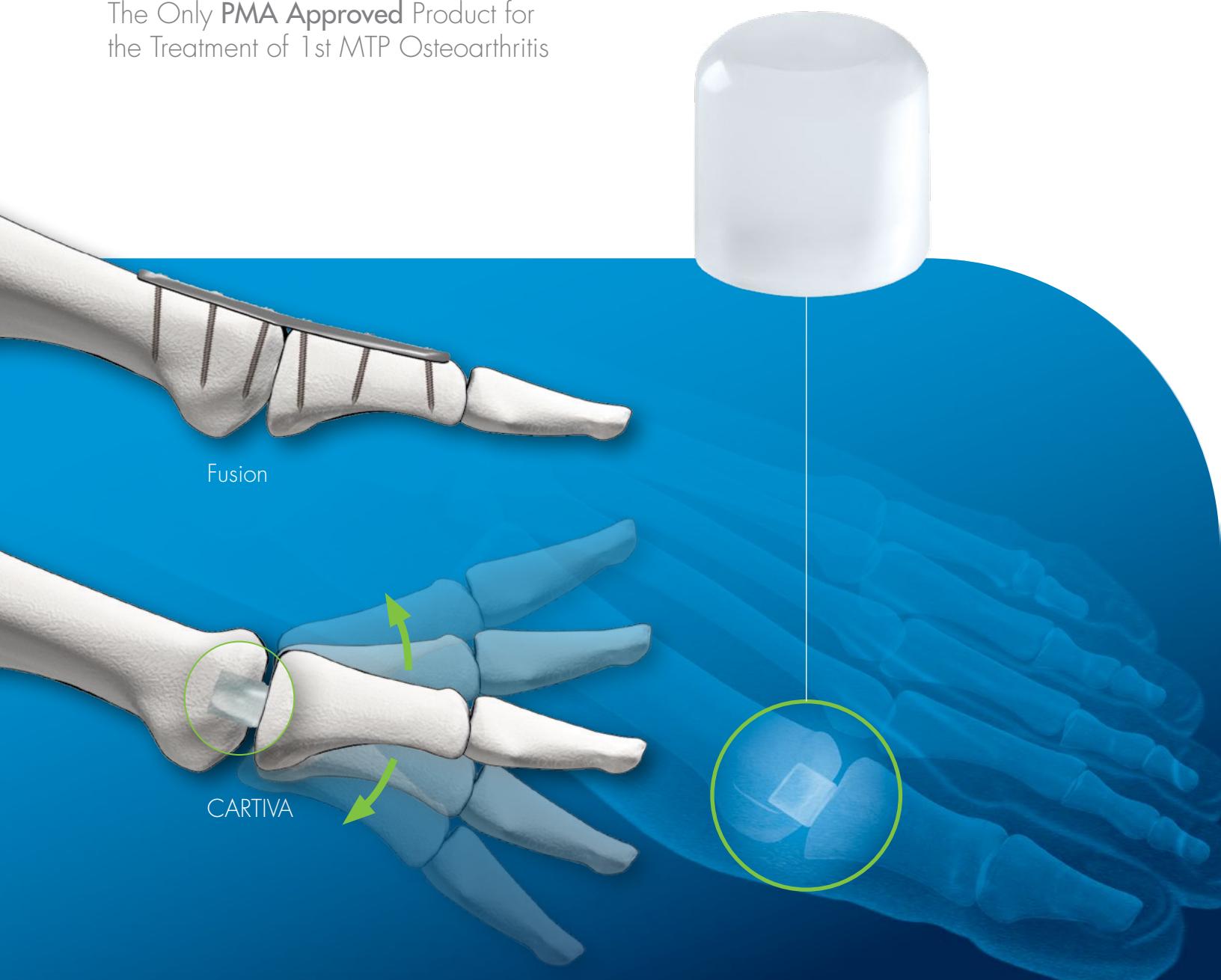


THE DIFFERENCE IS MOVING.™

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The Only **PMA Approved** Product for  
the Treatment of 1st MTP Osteoarthritis



# THE FIRST & ONLY PMA ALTERNATIVE TO FUSION + IMPROVED RANGE OF MOTION

**-93%**

SUBSTANTIAL  
REDUCTION IN PAIN

A substantial and clinically meaningful reduction in pain using the Visual Analog Scale (VAS) was experienced by subjects in the Cartiva implant group at every follow-up visit through 2 years. Cartiva implant subjects demonstrated a 93% reduction from a median score of 68 at baseline to 5 at 2 years.

**+168%**

SUBSTANTIAL FUNCTIONAL  
IMPROVEMENT

Functional activities were evaluated using the validated Foot and Ankle Mobility Measure (FAAM). Substantial improvement was observed for the Cartiva implant subjects throughout the 2-year follow-up period with a 168% median improvement observed in the sporting activities scale.

**+50%**

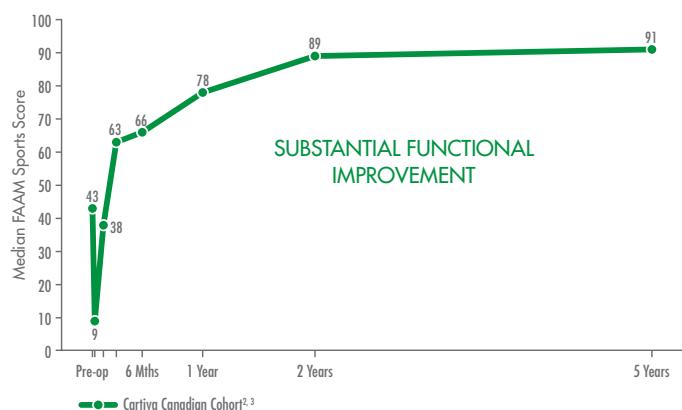
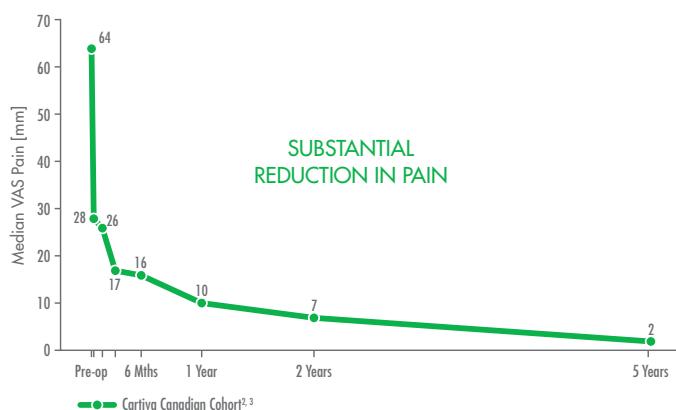
IMPROVED  
RANGE OF MOTION

There was a substantial and clinically important improvement in median active dorsiflexion motion in the Cartiva implant group, restoring motion to levels which are documented in the literature to be needed for normal walking gait while experiencing substantial reduction in pain.

**Level 1 Clinical Evidence<sup>1</sup>** of safety and effectiveness for treatment of 1st MTP Osteoarthritis, in the largest randomized study ever conducted for this condition.

**5-Year  
Data<sup>2,3</sup>**

**HIGH PATIENT SATISFACTION:**  
**96%** of patients would undergo procedure again



2. Daniels TR, Younger SE, Penner MJ, et al. Foot Ankle Int. 2017;38(3):243-247; N=27 in Cartiva Canadian 5-Year cohort.

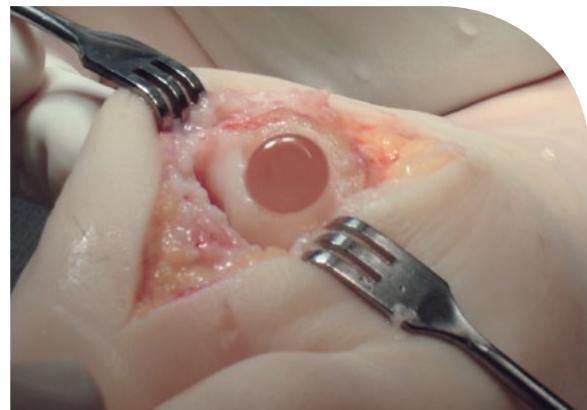
3. Data on file at Cartiva, Inc.

## FASTER THAN FUSION FAST & SIMPLE SURGICAL PROCEDURE

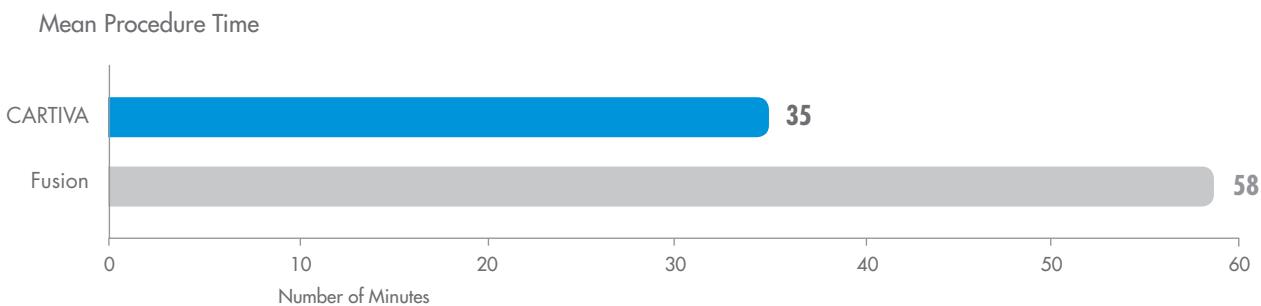
Cartiva® surgeries are **40%** (23 minutes) faster than fusion surgeries.<sup>4</sup>



*Illustration of the Cartiva device implanted into the metatarsal head*



*Damaged cartilage replaced with new Cartiva implant bearing surface*



## PATIENT BENEFITS QUICKER RECOVERY

Cartiva® SCI patients return to pre-operative activities faster than fusion patients.<sup>4</sup>



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

## HYDROGEL THAT WORKS LIKE NATURAL CARTILAGE

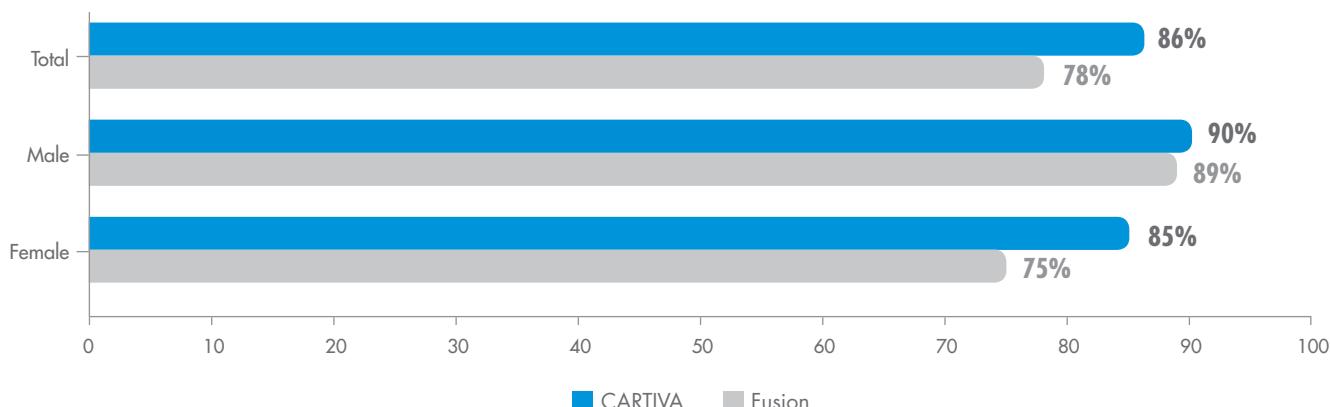
Mechanical and physical properties similar to native cartilage.

PROPERTY	ARTICULAR CARTILAGE <sup>3,5</sup>	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

### Patient Satisfaction

% of Patients that **would** have the procedure again.



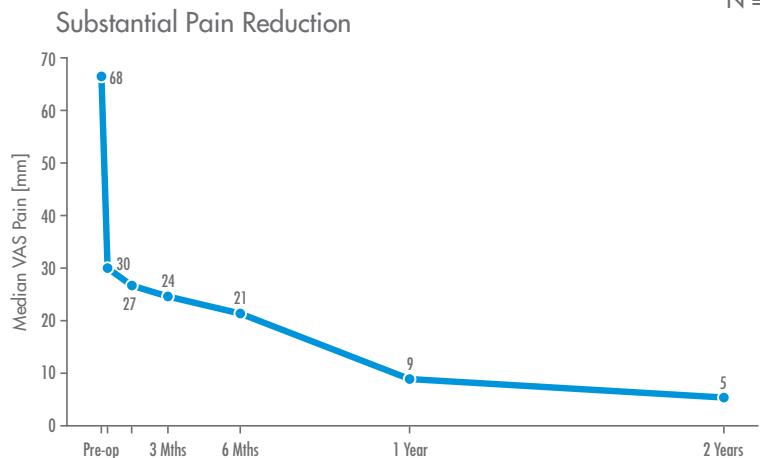
# PROVEN RESULTS

## CLINICAL STUDIES

Patients experience substantial reduction in pain, function improvement, and increased range of motion.

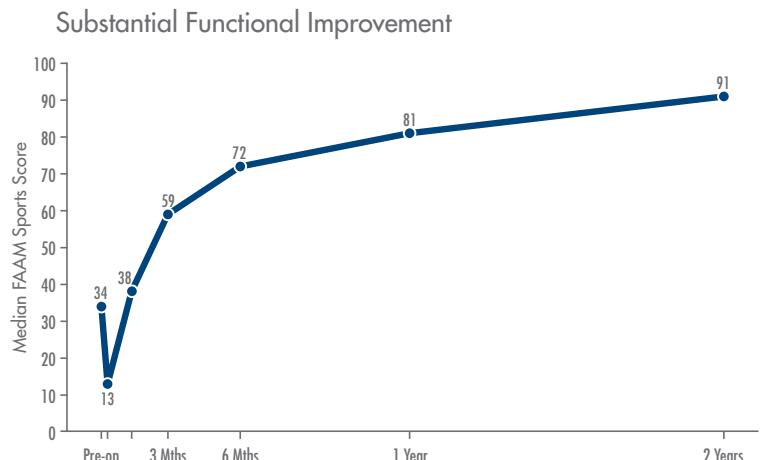
2 YEARS

N = 130



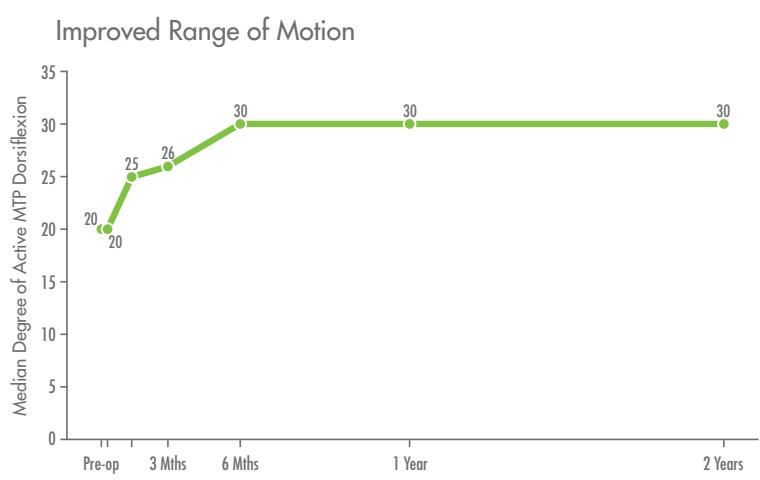
-93%

REDUCTION



+168%

IMPROVEMENT



+50%

IMPROVEMENT

# 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 Test Surface Axial Load	5 million Stainless Steel 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 Test Surface Simulated Axial Load	5 million Cartilage 4 MPa	- Resistance to wear demonstrated after 5M continuous cycles at simulated peak load of 4 MPa - 0.18% average mass loss (1.64mg) - Worse case wear debris over 5 years of 2.88 mg or 0.31% - Volumetric wear rate of 1.50mm <sup>3</sup> /yr that is considerably lower than UHMWPE (80mm <sup>3</sup> /year) <sup>6</sup>	
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 <sup>7</sup> MPa
		Equilibrium Elastic Compressive Modulus	2.68-3.34 MPa	0.54 <sup>8</sup> 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 <sup>9</sup> MPa (0.22-0.68 MPa)
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	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.		
S-N Analysis	Devices loaded in a confined fixture to 8, 12, 18, and 24 MPa out to 5,000,000 cycles	- Biphasic creep - 4-5% mass loss  - No catastrophic failure - Continuous 5M compression cycles - Extreme loads of 24 MPa (6 x peak load) - Even under significant stresses, no failures		

## ORDERING INFORMATION

For Customer Service Call: 877-336-4616

### IMPLANTS

#### CAR-10-US

10 mm Cartiva MTP Implant



#### CAR-08-US

8 mm Cartiva MTP Implant



### DRILL BITS

#### MTD-10

10 mm Counterbore Drill Bit



#### MTD-08

8 mm Counterbore Drill Bit



### GUIDE PINS

#### PNN-02

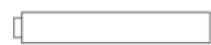
2 mm Guide Pin, Non-Threaded  
(6 per pack)



### 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



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.

## 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 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 Scale<sup>10</sup>

### CITATIONS:

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2. Daniels TR, Younger ASE, Penner MJ, et al. Mid-term Outcomes of Polyvinyl Alcohol Hydrogel Hemiarthroplasty of the First Metatarsophalangeal Joint in Advanced Hallux Rigidus. *Foot Ankle Int.* 2017;38(3):243-247; N=27 in Canadian 5-Year cohort.
3. Data on file at Cartiva, Inc.
4. Glazebrook MA, Younger ASE, Daniels TR, et al. Treatment of first metatarsophalangeal joint arthritis using hemiarthroplasty with a synthetic cartilage implant or arthrodesis: A comparison of operative and recovery time. *Foot Ankle Surg.* E-published in advance of print 2017-May 29.
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6. Jacobs CA, Christensen CP, Greenwald AS, McKellop H, Clinical performance of highly cross-linked polyethylenes in total hip arthroplasty. *J Bone Joint Surg Am.* 2007;89(12):2779-2786
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