CARTIVA®
Synthetic Cartilage Implant

The Only PMA Approved Product for the Treatment of 1st MTP Osteoarthritis
The Only **PMA Approved** Product for the Treatment of 1st MTP Osteoarthritis
THE DIFFERENCE IS MOVING.™

THE FIRST & ONLY PMA ALTERNATIVE TO FUSION

+ IMPROVED RANGE OF MOTION

Level I Clinical Evidence1 of safety and effectiveness for treatment of 1st MTP Osteoarthritis, in the largest randomized study ever conducted for this condition.

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 group at every follow-up visit through 2 years. Cartiva subjects demonstrated a 93% reduction from a score of 68 at baseline to 5 at 2 years.

-93%

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

+168%

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

+26%
Cartiva surgeries are 40% (23 minutes) faster than fusion surgery.

![Illustration of Cartiva SCI implanted into metatarsal head](image1)

![Damaged cartilage replaced with new Cartiva SCI bearing surface](image2)

In most operating rooms in the United States, the value of a minute can be as high as $100.?
PATIENT BENEFITS
QUICKER RECOVERY

Cartiva patients return to pre-operative activities faster than fusion surgery.

- 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.

<table>
<thead>
<tr>
<th>PROPERTY</th>
<th>ARTICULAR CARTILAGE</th>
<th>CARTIVA SCI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water Content</td>
<td>60-80%</td>
<td>60%</td>
</tr>
<tr>
<td>Compressive Modulus</td>
<td>0.3 – 0.8 MPa</td>
<td>2.5-3.2 MPa</td>
</tr>
<tr>
<td>Coefficient of Friction</td>
<td>&lt;0.01 – 0.05</td>
<td>0.04 – 0.07</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Total</th>
<th>CARTIVA</th>
<th>Fusion</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>78%</td>
<td>86%</td>
</tr>
<tr>
<td>Male</td>
<td>89%</td>
<td>90%</td>
</tr>
<tr>
<td>Female</td>
<td>75%</td>
<td>85%</td>
</tr>
</tbody>
</table>
Patients experience substantial reduction in pain, function improvement, and increased range of motion.

**PROVEN RESULTS**

**CLINICAL STUDIES**

**2 YEARS**

**Substantial Pain Reduction**

-93% REDUCTION

**Substantial Functional Improvement**

+168% IMPROVEMENT

**Improved Range of Motion**

+26% IMPROVEMENT
**EXTENSIVELY TESTED**

### BIOMATERIAL COMPATIBILITY OF CARTIVA SCI DEVICE

<table>
<thead>
<tr>
<th>Test</th>
<th>Method/Model</th>
<th>Result</th>
</tr>
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<tbody>
<tr>
<td>Cytotoxicity</td>
<td>L929 MEM Elution</td>
<td>Non-cytotoxic</td>
</tr>
<tr>
<td>Cytotoxicity</td>
<td>Direct Contact</td>
<td>Non-cytotoxic</td>
</tr>
<tr>
<td>Sensitization</td>
<td>Kligman Maximization</td>
<td>Non-sensitizer</td>
</tr>
<tr>
<td>Irritation/Intracutaneous</td>
<td>IC Injection</td>
<td>Negligible irritant</td>
</tr>
<tr>
<td>Acute Systemic Toxicity</td>
<td>Systemic Injection</td>
<td>Negative</td>
</tr>
<tr>
<td>Subchronic Toxicity</td>
<td>Femoral Condyle Implantation</td>
<td>Non-toxic</td>
</tr>
<tr>
<td>Chronic Toxicity</td>
<td>Femoral Condyle Implantation</td>
<td>Non-toxic</td>
</tr>
<tr>
<td>Genotoxicity</td>
<td>Ames Reverse Mutagen Assay</td>
<td>Non-mutagenic</td>
</tr>
<tr>
<td>Genotoxicity</td>
<td>Chromosomal Aberration Assay</td>
<td>Non-clastogenic</td>
</tr>
<tr>
<td>Genotoxicity</td>
<td>Rodent Bone Marrow Micronucleus</td>
<td>Non-clastogenic</td>
</tr>
<tr>
<td>Implantation</td>
<td>Bone Implantation In Femoral Condyle</td>
<td>Negative/no reaction</td>
</tr>
<tr>
<td>Pyrogenicity</td>
<td>Rabbit Pyrogen Test</td>
<td>Non-pyrogenic</td>
</tr>
</tbody>
</table>

### BIOMATERIAL COMPATIBILITY OF CARTIVA SCI INSTRUMENTATION

<table>
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</table>

### ANIMAL SAFETY STUDIES

**Animal Study**
- **1 Year Goat**
  - Cartiva device implanted in load bearing region of medial femoral condyle in stifles 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
  - 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
- Axial Load: 4 MPa
- Resistance to wear demonstrated after 5M continuous cycles at simulated peak load of 4 MPa
- 0.16% average mass loss (1.64mg)
- Worst case wear debris over 5 years of 2.88 mg or 0.31%
- Volumetric wear rate of 1.50mm³/yr that is considerably lower than UHMWPE (40mm³/year)

### 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

**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 whereas 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

**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
**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.

**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

**CITATIONS:**
1. Data on file at Cartiva.

**CARTIVA®**
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For Customer Service Call: 877-336-4616

**ORDERING INFORMATION**

**IMPLANTS**
- **CAR-10-US**
  - 10 mm Cartiva MTP Implant

- **CAR-8-US**
  - 8 mm Cartiva MTP Implant

**DRILL BITS**
- **MTD-10-US**
  - 10 mm Cartiva MTP Counterbore Drill

- **MTD-8-US**
  - 8 mm Cartiva MTP Counterbore Drill

**GUIDE PINS**
- **PNN-02-US**
  - 2 mm Guide Pin, Non-Threaded (6 per pack)

**INTRODUCTORS**
- **INT-10-US**
  - 10 mm Introducer

- **INT-8-US**
  - 8 mm Introducer

**PLACERS**
- **PLC-10-US**
  - 10 mm Placer

- **PLC-8-US**
  - 8 mm Placer

**DELIVERY TRAY**
- **TRA-05-US**
  - Delivery 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 reused or re-implanted. Ensure proper alignment and placement of device components as misalignment may cause excessive wear and/or early failure of the device.