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 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 I Clinical Evidence\(^1\) of safety and effectiveness for treatment of 1st MTP Osteoarthritis, in the largest randomized study ever conducted for this condition.

EXCELLENT SURVIVORSHIP: 96.2% implants retained
HIGH PATIENT SATISFACTION: 96% of patients would undergo procedure again

5-Year Data\(^2\)

SUBSTANTIAL REDUCTION IN PAIN

SUBSTANTIAL FUNCTIONAL IMPROVEMENT
Cartiva® surgeries are 40% (23 minutes) faster than fusion surgeries.

Illustration of the Cartiva device implanted into metatarsal head

Damaged cartilage replaced with new Cartiva implant bearing surface

Mean Procedure Time

<table>
<thead>
<tr>
<th>Procedure Type</th>
<th>Mean Procedure Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>CARTIVA</td>
<td>35</td>
</tr>
<tr>
<td>Fusion</td>
<td>58</td>
</tr>
</tbody>
</table>

In most operating rooms in the United States, the value of a minute can be as high as $100.²
Cartiva® SCI patients return to pre-operative activities faster than fusion patients.

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

Patient Satisfaction
% of Patients that would have the procedure again.

<table>
<thead>
<tr>
<th>PROPERTY</th>
<th>ARTICULAR CARTILAGE</th>
<th>CARTIVA</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

Mechanical and physical properties similar to native cartilage.
Patients experience substantial reduction in pain, function improvement, and increased range of motion.

**Substantial Pain Reduction**

- Median VAS Pain [mm]:
  - Pre-op: 68
  - 3 Mths: 27
  - 6 Mths: 24
  - 1 Year: 9
  - 2 Years: 5

**Substantial Functional Improvement**

- Median FAAM Sports Score:
  - Pre-op: 13
  - 3 Mths: 34
  - 6 Mths: 50
  - 1 Year: 72
  - 2 Years: 91

**Improved Range of Motion**

- Median Degree of Active MTP Dorsiflexion:
  - Pre-op: 20
  - 3 Mths: 25
  - 6 Mths: 30
  - 1 Year: 30
  - 2 Years: 30

**Proven Results**

CLINICAL STUDIES

-93% REDUCTION
+168% IMPROVEMENT
+50% IMPROVEMENT

N = 130
### Extensively Tested

**Biocompatibility of Cartiva Device**

<table>
<thead>
<tr>
<th>Test</th>
<th>Method/Model</th>
<th>Result</th>
</tr>
</thead>
<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 Mutation</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>
</tbody>
</table>

**Biocompatibility of Cartiva Instrumentation**

<table>
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<tr>
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<td>IC Injection</td>
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### 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.

- No complications on injection
- No test-article related adverse changes
- No significant findings on clinical observation, gross pathology, histomorphometry, or histopathology of localized tissue
- No wear debris or foreign body giant cells with injected material

### Functional Testing

**Fatigue Testing**

- Cycles: 5 million
d- Test Surface: Stainless Steel
d- 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
d- Test Surface: Cartilage
d- 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 (1.64mg)
- Worse 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 (80mm3/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

<table>
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<tr>
<th>CARTIVA</th>
<th>Articular Cartilage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compressive Modulus</td>
<td>3.05 ±0.12 MPa</td>
</tr>
<tr>
<td>Equilibrium Elastic</td>
<td>2.68–3.34 MPa</td>
</tr>
</tbody>
</table>

**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 ±1.1 MPa where cartilage values range between 0.6 and 1.2 MPa.

<table>
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<th>CARTIVA</th>
<th>Articular Cartilage</th>
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<tbody>
<tr>
<td>Shear Moduli</td>
<td>0.18–0.36 MPa</td>
</tr>
</tbody>
</table>
| Creep                   | 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

- 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-8-US
8 mm Cartiva MTP Implant

DRILL BITS

MTD-10
10 mm Counterebore Drill Bit

MTD-8
8 mm Counterebore Drill Bit

GUIDE PINS

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

INTRODUCERS

INT-10
10 mm Introducer

INT-8
8 mm Introducer

PLACERS

PLC-10
10 mm Placer

PLC-8
8 mm Placer

DELIVERY TRAY

TRA-05-US
Delivery 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 device 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

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 use 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:

1. Data on file at Cartiva, Inc.