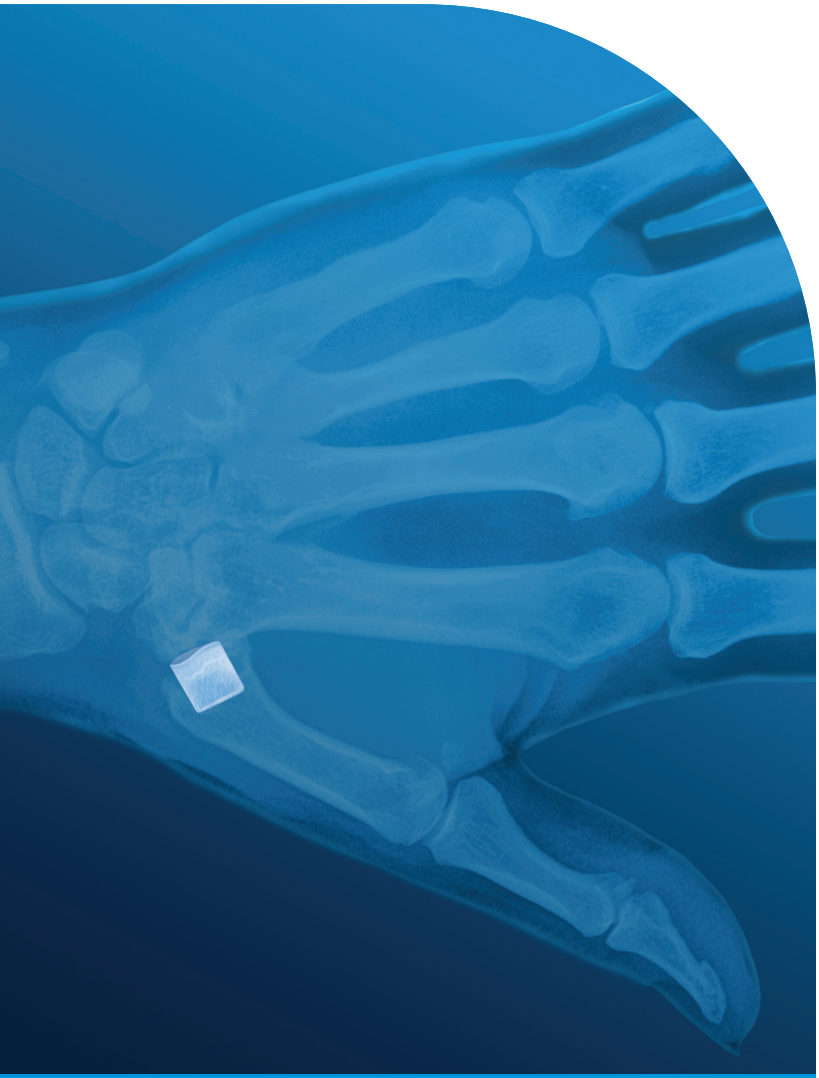
CARTIVA®

Synthetic Cartilage Implant

For the Treatment of CMC Joint Osteoarthritis



HAND CMC Joint

THE DIFFERENCE IS STRENGTH.

For OUS Distribution Only

THE DIFFERENCE IS **STRENGTH.**

The Cartiva® implant does not shorten the metacarpal bone, thereby maintaining the normal anatomy, which contributes to improved key pinch, tip pinch, and grip strength.

+100%

KEY PINCH STRENGTH[1]

+109%

TIP PINCH STRENGTH[1]

+82%

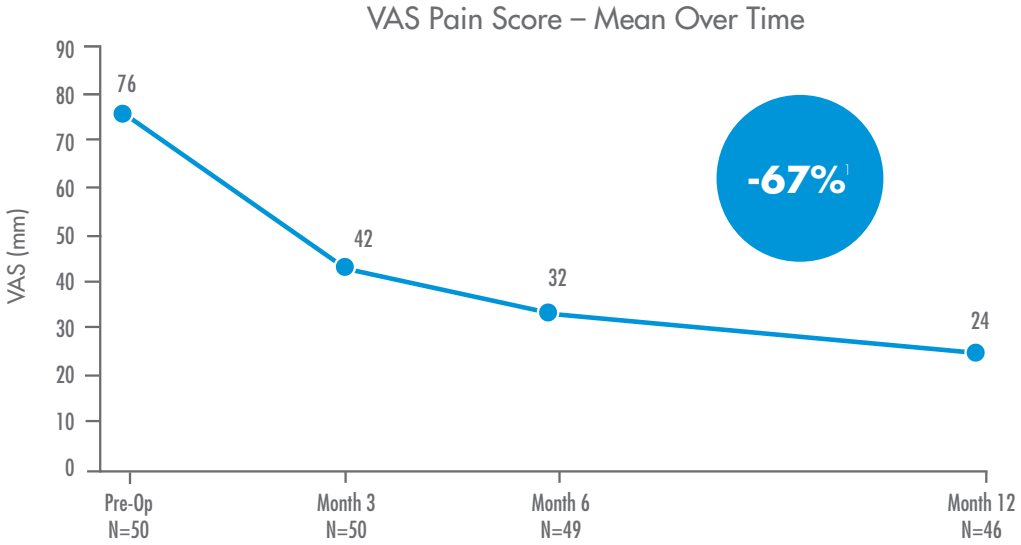
GRIP STRENGTH[1]

Improvements as reported in the literature for trapeziectomy with or without LRTI for key pinch, tip pinch, and grip strength range from 12.5% to 15%, 17.2% to 18.5%, and 27% to 35%, respectively.[2]

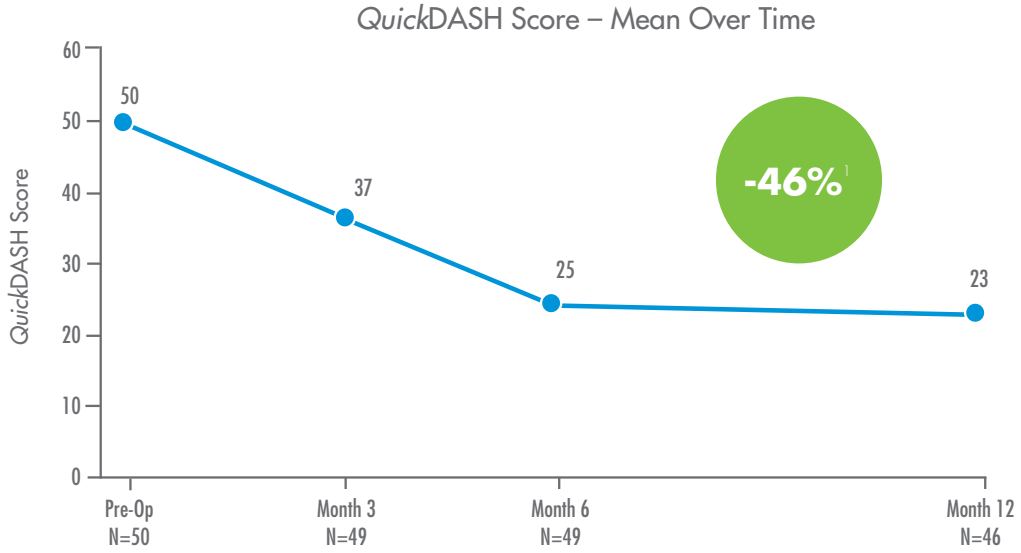
A unique biomedical polymer that mimics natural cartilage and aids in smooth joint articulation and mobility.[3]

THE DIFFERENCE IS DATA.™

Unlike LRTI and Trapeziectomy, Cartiva® maintains the normal anatomy by sparing the trapezium and preserving joint height.



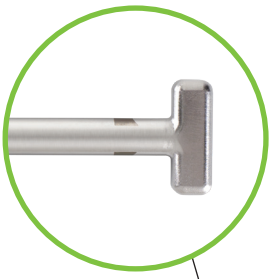
A substantial and clinically meaningful reduction in pain using the Visual Analog Scale (VAS) was observed for Cartiva patients at 12 months. 80% of Cartiva implant patients demonstrated a clinically meaningful reduction in pain from baseline at 12 months.[1,4]



Functional activities were evaluated using the QuickDash. A substantial reduction (improvement) was observed in the mean QuickDash scores at 12 months. 94% of Cartiva implant patients demonstrated a clinically meaningful reduction in disability (improvement in function) from baseline at 12 months.[1,5]

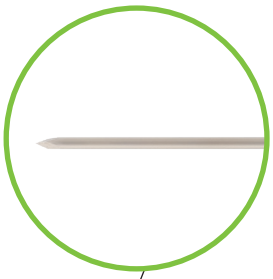
CARTIVA® INSTRUMENTATION

Cartiva is implanted using dedicated instrumentation designed to provide the surgeon with an implant that is well-seated through a press-fit implantation.



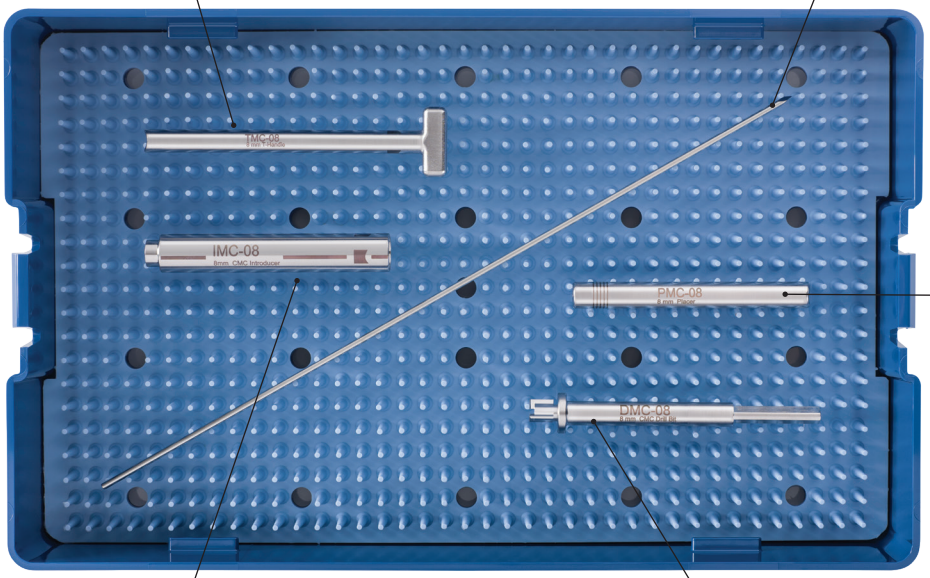
T-Handle

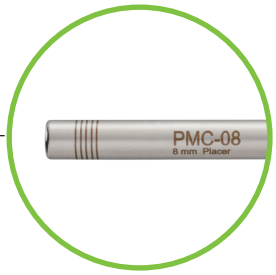
Allows surgeon to advance the implant through the introducer and into the cavity.



Guide Wire

2.0 mm non threaded.





Placer

Allows surgeon to target optimal implant position.

Introducer

Compresses Cartiva prior to implantation.

No fixation required.

Metacarpal Drill Bit

Stop to ensure proper height of press-fit implant.

HYDROGEL THAT WORKS
LIKE NATURAL CARTILAGE

Mechanical and physical properties similar to native cartilage.

PROPERTY	ARTICULAR CARTILAGE[7,8]	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

CARTIVA VS. LRTI

Cartiva SCI does not "burn a bridge" to excellent pain relief and successful functional outcomes, if a revision procedure is needed.[6]

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 100,000 Test Surface Stainless Steel Axial Load 54 MPa	- Mechanical durability demonstrated after 100,000 continuous cycles at peak load of 54 MPa - Significant mass and height recovery upon unloading - The Cartiva device demonstrated adequate strength to survive the repetitive, compressive loads that occur clinically
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 - Average total mass of debris collected per device over 5 million cycles was 0.31% of the initial mass of the test articles. - Worse case wear debris over 5 years of 2.88 mg or 0.31% of initial device mass - Volumetric wear rate of .53 mm3/yr that is considerably lower than UHMWPE (80 mm3/year)[9]
Torsion	Devices seated in foam bone analog inferior fixture, compressed at 1mm, 2mm, or 3mm of displacement, and then rotated to apply 10 degrees of torsion to simulate worst-case torsion conditions	All specimens at all three compression levels of 1 mm, 2 mm, and 3 mm did not exhibit any rotation within the test fixture or any damage due to the applied torsion. The lack of rotation ensures no wear at the device-bone socket interface and, consequently, no loosening or implant dislodgement.
S-N Analysis	Devices loaded in a confined fixture to 8, 12, 18, and 24 MPa out to 5,000,000 cycles and 12, 35, and 54 MPa to 100,000 cycles	- No catastrophic failure - Continuous 5M compression cycles - Extreme loads of 24 MPa (6 x peak load) - Even under significant stresses, no failures
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 proud and loaded at 45 degrees to apply axial compression and worst-case lateral shear to demonstrate no tearing or dislocation	All test articles reached 3 mm of displacement without dislocations or tearing. The devices fully recovered to initial height and mass post-test.
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

CARTIVA® PRODUCTS FOR CMC

IMPLANTS

CMC-08
8 mm Cartiva CMC Implant

For Customer Service Call: 877-336-4616

REUSABLE INSTRUMENTATION

DRILL BITS

DMC-08
8 mm Cartiva CMC Counterbore Drill

PLACERS

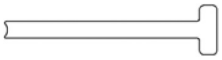
PMC-08
8 mm CMC Placer

GUIDE PINS

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

T-HANDLE

TMC-08
8 mm CMC T-Handle

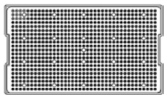


INTRODUCERS

IMC-08
8 mm CMC Introducer

STERILIZATION TRAY

TRA-00
Sterilization Tray



BRIEF SUMMARY OF IMPORTANT PRODUCT INFORMATION

INDICATIONS FOR USE

Cartiva SCI for CMC is indicated for use in treatment of diseased or damaged articular surface of the first carpometacarpal joint.

CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS

Contraindications:

Cartiva SCI for CMC is not designed, sold, or intended for use other than as indicated.

Use of the device is contraindicated for patients with the following:

- Any significant bone loss, avascular necrosis, or subchondral bone cyst > 8mm of the supporting bone structure;
- Inadequate cortical bone stock required to support placement of the implant;
- Inflammatory arthropathy and/or diagnosis of gout;
- 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, immunosuppressive therapies, neuromuscular compromise, vascular deficiency in the affected limb, absence of musculoligamentous supporting structures, and joint neuropathy), tumors and/or cysts of the supporting bone structures, arthritis of the scaphotrapeziotrapezoidal (STT) joint, rheumatoid arthritis, or joints previously treated with trapeziectomy;
- Known or suspected allergic reaction to polyvinyl alcohol;
- Active infection of the surgery site;
- Patient is on chronic anticoagulation due to a bleeding disorder or has taken anticoagulants within 5 days prior to surgery.

Warnings and Precautions:

It is the responsibility of each surgeon utilizing the Cartiva SCI for CMC device to consider the clinical and medical status of each patient and to be knowledgeable about all aspects of implant procedures and the potential complications that may occur. The benefits derived from implant surgery may not meet the patient's expectations or may deteriorate with time, necessitating revision surgery to replace the implant or to carry out alternative procedures. Revision surgeries with implants are not uncommon. Surgeons must balance many considerations to achieve the best result in individual patients.

Clinical results depend on physician and technique, preoperative and postoperative care, the implant, patient pathology, and daily activity. It is suggested that surgeons use appropriate informed consent and discuss the potential for complications and the use of alternative techniques with each patient scheduled for surgery.

The Cartiva implant is a single-use only device. Each device should be used in one patient, during one procedure, and in only one implant site. Re-use of a previously-implanted device is strictly prohibited. Material properties required for implant duration and longevity cannot be assured by the manufacturer if the device is re-used, and the potential cross-contamination between implant sites and/or patients poses a serious health risk.

Cartiva SCI for CMC has been sterilized. The implant is not compatible with gas or steam (autoclave) sterilization. DO NOT RESTERILIZE THE IMPLANT.

The implant is not compatible with storage or shipment temperatures in excess of 49°C (120°F). If the temperature-sensitive indicator on the container has turned dark gray to black, DO NOT USE THE IMPLANT.

Physical activity should be resumed according to the rehabilitation plan recommended by the physician. Vigorous activity may compromise the durability of clinical benefit from Cartiva SCI for CMC.

The long-term safety and effectiveness of cartilage replacement are unknown.

Safety and effectiveness of Cartiva SCI for CMC in the following populations have not been established:

- Pediatric population;
- Pregnant women;
- Patients with either systemic or local infections;
- Patients with a diagnosis of concomitant injury that the physician believes may interfere with healing;
- Patients with clinically significant (as defined by the surgeon) renal, hepatic, cardiac, endocrine, hematologic, autoimmune or any systemic disease which may make interpretation of the results difficult;
- Patients who have undergone systemic administration within 30 days prior to implantation of any type of corticosteroid in the thumb, antineoplastic, immunostimulating or immunosuppressive agents;
- Patients with evidence of osteonecrosis of the involved joint, or history of peripheral neuropathy, active or on-going neoplastic disease, or immunosuppression.

To avoid dehydration, maintain the Cartiva SCI for CMC in sterile saline until ready to implant.

CITATIONS:

1. Data on file at Cartiva; n = 49 @ 12 months, GRIP Study.
2. Salem H, Davis TRC. Six year outcome excision of the trapezium for trapeziometacarpal joint osteoarthritis: is it improved by ligament reconstruction and temporary Kirschner wire insertion? J Hand Surg Eur. 2011 May;37E(3):211-219.
3. Oka M, Ushio K, Kumar P, Ikeuchi K, Hyon SH, Nakamura T, Fujita H. Development of artificial articular cartilage. Proc Inst Mech Eng H. 2000;214(1):59-68.
4. Dworkin RH, et al. Interpreting the clinical importance of treatment outcomes in chronic pain clinical trials: IMMPACT recommendations. J Pain. 2008 Feb;9(2):105-21. Epub 2007 Dec 11.
5. Franchignoni, Franco, et al. "Minimal clinically important difference of the disabilities of the arm, shoulder and hand outcome measure (DASH) and its shortened version (*Quick*DASH)." journal of orthopaedic & sports physical therapy 44.1 (2014): 30-39.
6. Bainbridge L.C., et al. "A prospective, multicenter clinical trial to assess safety and efficacy of a synthetic cartilage implant for treatment of Eaton-Littler stage II/III first CMC joint osteoarthritis: Cartiva GRIP Trial." BSSH Abstract. 2017 July 14; Abstract Ref 31911.
7. Data on file at Cartiva, Inc.
8. Baker MI, Walsh SP, Zvi Sc, Boyan BD. J Biomed Mater Res B Appl Biomater. 2012 Jul;100(5):1451-7.
9. Jacobs CA, Christensen CP, Greenwald AS, et al. J Bone Joint Surg Am. 2007;89(12):2779-2786.
10. Korhonen RK, Laasanen MS, Toyras J, et al. J Biomech. 2002 Jul;35(7):903-909.
11. Jurvelin JS, Buschmann MD, Hunziker EB, J Biomechanics. 1997;30(3):235-241.

CARTIVA®

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Cartiva's Synthetic Cartilage Implant is not approved for use in the 1st CMC joint in the United States Currently only available for use in Europe and Canada.

B30-0773 Rev. A