

CARTIVA[®]

Synthetic Cartilage Implant

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

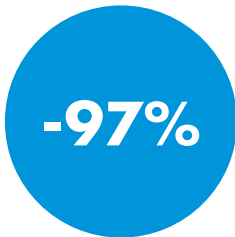


FOOT

First MTP Joint

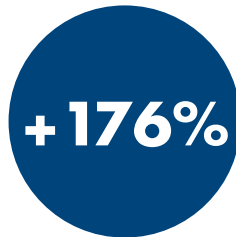
THE DIFFERENCE IS MOVING.™

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



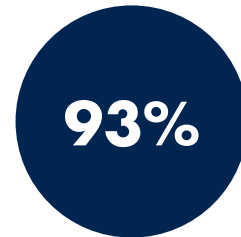
SUBSTANTIAL REDUCTION IN PAIN

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



SUBSTANTIAL FUNCTIONAL IMPROVEMENT

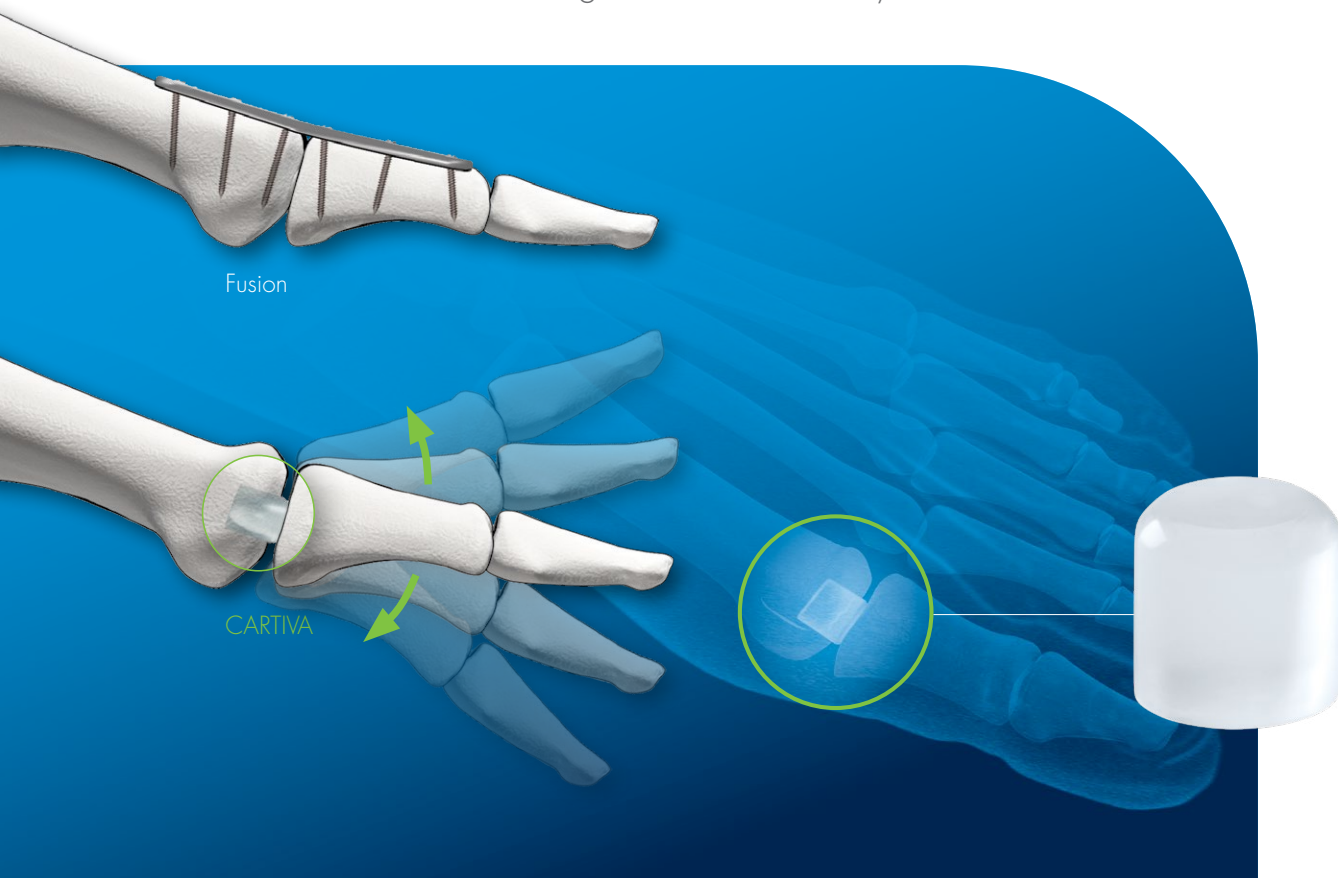
Functional activities were evaluated using the validated Foot and Ankle Mobility Measure (FAAM). A substantial and clinically meaningful improvement was observed in the median FAAM sports score at the 5.8 year follow-up with Cartiva patients reporting a 176% median improvement in the sporting activities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



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



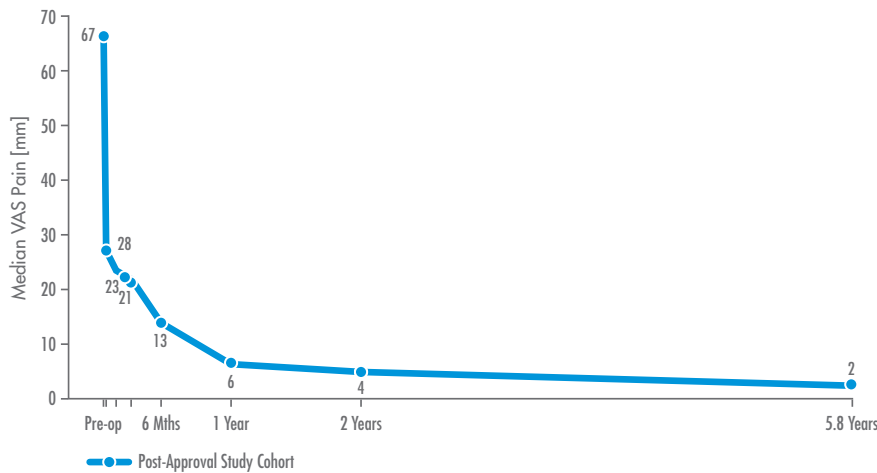
THE FIRST & ONLY PMA ALTERNATIVE TO FUSION + PROVEN LONGEVITY

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

5.8 YEARS

Substantial Pain Reduction²

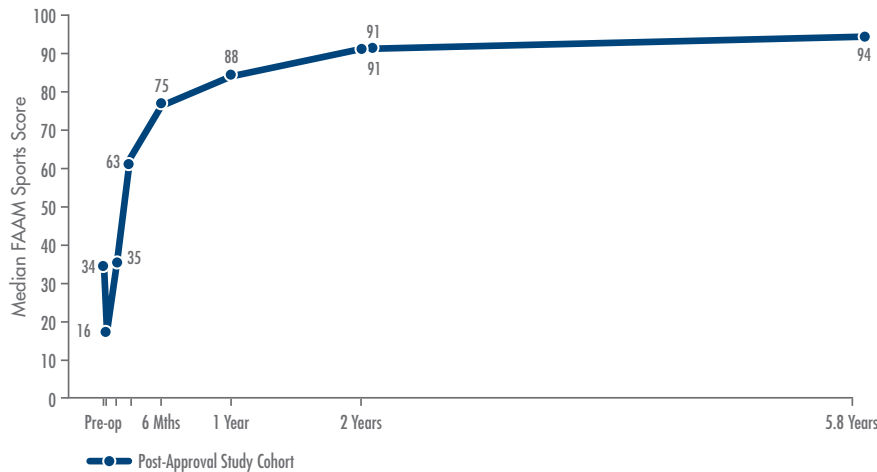
N = 106



-97%
REDUCTION

Substantial Functional Improvement²

N = 105



+176%
IMPROVEMENT

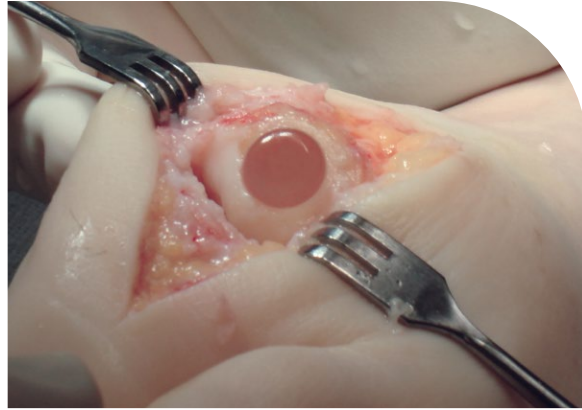
FASTER THAN FUSION

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

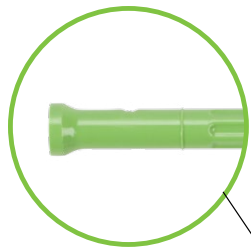
- First new articular surface material **approved by FDA** in 17 years
- The only FDA approved **cartilage-like polymer**
- **Proven effective** in the largest, longest multi-center trial ever conducted for first MTP OA¹
- Study data evaluated as **low risk of bias** in comprehensive published review⁴
- 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

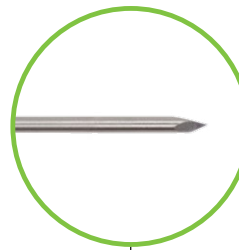
Cartiva's next generation instrumentation is a **compact, off-the-shelf set** that provides surgeons with new, sterile instrumentation for every single surgery. No post-op reprocessing saves costs and improves efficiencies for facilities.



Placer

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

Depth gauge to provide confirmation of cavity depth.

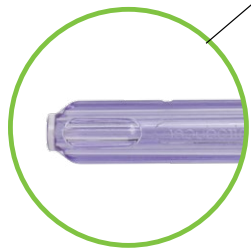


Placement Guide Pin

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

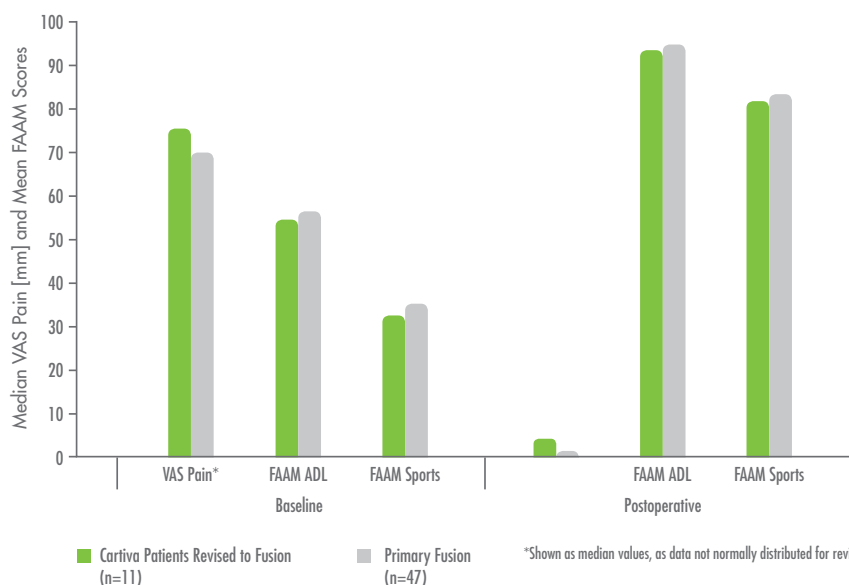
Mechanical and physical properties similar to native cartilage.

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	I929 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	I929 MEM Elution		Non-cytotoxic	
Sensitization	Kligman Maximization		Non-sensitizer	
Irritation/Intracutaneous	IC Injection		Negligible irritant	
ANIMAL SAFETY STUDIES				
Animal Study 1 Year Goat	<p>Cartiva device implanted in load bearing region of medial femoral condyle in stifle of 8 mature goats; control defects in 4 goats</p> <p>At one year, knees evaluated via</p> <ul style="list-style-type: none"> - High field strength MR imaging system for morphology and quantitative T2 and T1-rho parameters; - Histological processing - Biomechanical testing 		<ul style="list-style-type: none"> - 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	<ul style="list-style-type: none"> - 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. <p>At 3 and 6 months, histology and pathology per ISO standards</p>		<ul style="list-style-type: none"> - 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	<p>Cycles 5 million</p> <p>Test Surface Stainless Steel</p> <p>Axial Load 4 MPa</p>		<ul style="list-style-type: none"> - 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	<p>Cycles 5 million</p> <p>Test Surface Cartilage</p> <p>Simulated Axial Load 4 MPa</p>		<ul style="list-style-type: none"> - 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	<ul style="list-style-type: none"> - Biphasic creep - 4-5% mass loss 		
SN Analysis	Devices loaded in a confined fixture to 8, 12, 18, and 24 MPa out to 5,000,000 cycles	<ul style="list-style-type: none"> - 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



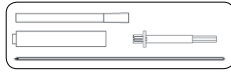
CAR-08-US

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



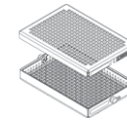
PLC-08

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 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 Scale¹³

CITATIONS:

1. Baumhauer JF, Singh D, Glazebrook M, et al. *Foot Ankle Int.* 2016;37(5):457-469; N=130 in Cartiva pivotal trial cohort.
2. Data on file at Cartiva, Inc. N=106 in post-approval study cohort.
3. Glazebrook MA, Younger ASE, Daniels TR, et al. *Foot Ankle Surg.* 2017;May-29.
4. Stevens J, de Bot RT, Hermus JP, et al. *JBJs reviews* 5.11 (2017): e2.
5. Baumhauer JF, Singh D, Glazebrook M, et al. *Foot Ankle Int.* 2017 Nov;38(11):1175-1182.
6. Data on file at Cartiva, Inc.
7. Baker MI, Walsh SP, Zvi SC, Boyan BD. *J Biomed Mater Res B Appl Biomater.* 2012 Jul;100(5):1451-7.

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.

8. Glazebrook M, Baumhauer J, Davies MB. *Foot & Ankle Orthopaedics.* 2017 Sep 11;2(3):2473011417S000044.
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.
12. Athanasios KA, Liu GT, Lavery LA, et al. *Clin Orthop Relat Res.* 1998 Mar;348:269-281.
13. Coughlin MJ, Shumas PS. *American Journal of Bone Joint Surgery.* 85-A(11):2072-88. November 2003.

CARTIVA®

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