Cartiva, Inc.
Instructions For Use

Cartiva® Synthetic Cartilage Implant (SCI) Instructions for Use

DEVICE DESCRIPTION
Cartiva® Synthetic Cartilage Implant (SCI) is intended to treat focal chondral or osteochondral defects of the articular cartilage surface associated with joint pain or decreased range of motion. The implant, a cylindrical device made from an elastic biomaterial, may be used as a replacement for damaged cartilage and bone without requiring the destruction or removal of a patient's healthy tissue. It is intended for use during a single surgical procedure. The procedure is similar to that used for osteochondral autograft or allograft transplantation; a part is placed into a pre-drilled hole to resurface the damaged area of cartilage/bone.

Cartiva® SCI is made from a proprietary biomaterial. The device, which is classified as a hydrated polymer, consists of water in similar proportion to human tissue. This organic polymer-based biomaterial is capable of withstanding repetitive loading typical of normal walking conditions, and its mechanical properties are similar to articular cartilage. Cartiva® SCI provides an alternative to tissue-based treatments without exposing the patient to the risk of viral transmission or an inflammatory response because it does not contain substances derived from human or animal tissue.

Cartiva® SCI is supplied in a range of sizes for selection by the physician. The device is supplied sterile and is packaged as a single unit.

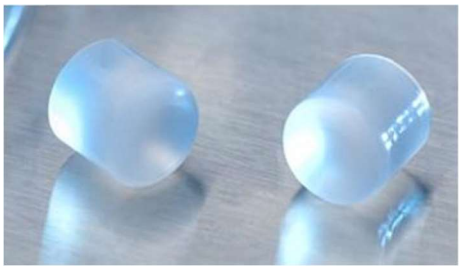


Figure 1 Cartiva Synthetic Cartilage Implant

Cartiva SCI is manufactured in three sizes for treatment of first metatarsophalangeal joint osteoarthritis:

Cartiva SCI Implant Sizes		
6 mm	**8 mm**	**10 mm**
(6 mm diameter x 8 mm depth)	(8 mm diameter x 8 mm depth)	(10 mm diameter x 10 mm depth)

The Cartiva SCI device is implanted using instruments specifically designed for placement of the device. The Cartiva SCI instrumentation is used to drill an appropriately sized cavity in the metatarsal head and deploys the Cartiva SCI device into the prepared cavity.

INDICATIONS
The Cartiva Synthetic Cartilage Implant (SCI) is intended for use in the treatment of patients with degenerative or post-traumatic arthritis in the first metatarsophalangeal joint in the presence of good bone stock along with the following clinical conditions: hallux valgus or hallux limitus, hallux rigidus, and an unstable or painful metatarsophalangeal (MTP) joint.

CONTRAINDICATIONS
The Cartiva SCI should not be implanted in subjects with the following conditions:

- Active, old, or remote infection. Every effort should be undertaken to rule out pre-operative infection in a patient with suspicious symptoms such as a history of, or when there are signs of, local inflammation, abscesses, fever, increased erythrocyte sedimentation rate, evidence of rapid joint destruction, or bone resorption.
- Large areas of bone loss, avascular necrosis, or large subchondral bone cysts
- Lesions of the first metatarsal head greater than 10 mm in size
- 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), and/or tumors and/or cysts >1cm of the supporting bone structures, and suspected allergic reaction to polyvinyl alcohol.
- Severe instability secondary to advanced loss of muscle, ligament or soft tissue integrity.

WARNINGS
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 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.

PRECAUTIONS

POTENTIAL COMPLICATIONS AND ADVERSE REACTIONS
An implant site may become infected, painful, swollen, or inflamed. Risks associated with implantation of hemi-arthroplasty devices or Cartiva Synthetic Cartilage Implant include bony reaction, implant loosening, implant dislocation/dislodgement, cysts, bony erosion, and device wear.

Undesirable implant performance may be caused by:
- Inappropriate patient selection
- Leaving an insufficient (< 5mm at surface and base) bone bridge between implants when placing two in the same articular area
- Incorrect drill hole size for implant
- Incorrect depth of implant placement
- Uncorrected joint malalignment
- Uncorrected joint instability
- Unrecognized or uncorrected cartilage pathology in the non-operated compartment(s)
- Excessive early post-operative load bearing

Some preventive measures to consider in order to minimize the potential for complications:
- Follow accepted patient selection guidelines
- Identify and correct co-existing pathology
- Ensure appropriate implant placement
- Use a properly sized implant and drill bit for each implant used in the procedure

If complications develop, possible corrective procedures include:
- Replacement of implant(s)
- Implant removal
- Autograft or allografting of the implant site

PRIOR TO USE
1. Before presentation to the operative field, inspect the package to ensure sterility has not been breached during transportation. If the package is obviously damaged or if there is a question of sterility for any other reason, DO **NOT** USE THE IMPLANT.

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

3. The contents of the pouch, including the tray and implant, are sterile. The carton and exterior of the container is not sterile. DO **NOT** PRESENT THE INTACT CARTON OR POUCH TO THE OPERATIVE FIELD.

4. Inspect each Cartiva SCI implant to ensure that it is not hard, brittle, torn, or otherwise defective. If any of these problems is detected, DO **NOT** USE THE IMPLANT.

DIRECTIONS FOR USE

Reference the *Cartiva Synthetic Cartilage Surgical Implantation Technique Guide* for further information.

Cartiva SCI is implanted using dedicated accompanying instrumentation designed to provide the surgeon and subject with an implant that is well-seated through a press fit implantation. The implantation procedure is similar to that used for osteochondral autograft or allograft transplantation, where a defect area is removed and resurfaced.

Implantation of Cartiva SCI device has been validated for use with surgical instrumentation distributed by Cartiva, Inc. The instruments are provided non-sterile and require sterilization prior to use. The Cartiva SCI Instrumentation have been validated for their intended function and use with a cannulated drill and 2 mm diameter non-threaded guide pin (minimum length 200 mm), and are specific to the size of the device being implanted. The following table references optimal dimensions for successful implantation of Cartiva SCI implants slightly proud (~0.5-1.5 mm) with the surrounding cartilage:

Table 1 Cartiva SCI Specifications of Implant Site

Lesion size	Implant	Drill Part	Hole Diameter	Hole Depth
Up to 6 mm	CAR-06	MTD-06	6.0 mm	8.5 mm
6 mm to 8 mm	CAR-08	MTD-08	7.9 mm	8.3 mm
8 mm to 10 mm	CAR-10	MTD-10	9.5 mm	10.0 mm

Access the affected joint using standard surgical technique. Care should be taken to avoid nerve damage along the dorso-medial aspect of the joint. Expose the entire joint to gain access to the central metatarsal head. Resect any osteophytes from the proximal phalanx and/or metatarsal head, ensuring adequate bone stock is preserved for insertion and stability of the implant. Confirm the appropriate size implant to be used by using the concave end of the appropriate Placer size on the metatarsal head.

Ensure that the appropriate size Cartiva® SCI implant is available to complete the repair (see table above). Once the appropriate size is determined, use the concave end of the Placer to create a perpendicular angle to the metatarsal head, and to identify the target implantation site. The Placer should be positioned relatively central but can be positioned slightly asymmetric so as to address the worst area of arthritic involvement on the metatarsal head. Cartiva requires a minimum of 2mm of surrounding bone stock. Insert the Guide Pin into the center of the defect.

Select the appropriate Drill Bit (MTD-06, MTD-08 or MTD-10) to drill a hole into the subchondral bone to the proper depth (recommendations can be found in the table above). The Drill Bit should match the selected implant size to achieve a tight fit with the implant. Insert the Drill Bit over the Guide Pin and advance the drill until the stop is flush with the surrounding metatarsal head surface. Care should be taken to advance only to the drill stop using light pressure and to irrigate while drilling. Note the Placement Guide Pins are single use.

If necessary, remove any cartilage and/or bone debris from the recipient implant site.

Remove implant from packaging using smooth forceps. Moisten the inner walls of the Introducer tube with sterile saline. Place the Cartiva SCI implant into the proximal (wide) end of the Introducer with the flat side of the implant facing distally (rounded side facing proximally) so that the flat side of the implant will be placed in the bottom of the recipient implant site. Insert the smaller, flat end of the Placer into the wide end of the Introducer. Rest the distal end of the Introducer on a flat, non-shedding, sterile surface and insert the smaller, flat end of the Placer into the proximal end of the Introducer. Apply pressure to the larger, concave end of the Placer to slowly advance the implant to the distal end of the Introducer. Do not advance the flat side of the implant beyond the distal end of the Introducer until ready to deliver the implant to the recipient site. Place the distal end of the Introducer at (but not into) the recipient implant site. Advance the Cartiva SCI implant into the implant site using the Placer. Continue to apply steady pressure to the concave end of the Placer until the flat side of the implant reaches the bottom of the recipient site. Remove the Introducer and Placer.

Confirm that the implant is seated firmly in the base of the recipient site and is tight within it. The implant should be slightly proud (~ 0.5 to 1.5 mm) in the implant site.

HANDLING

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

Cartiva® SCI Instrumentation
Non-sterile Instruments Care and Instructions for Use

INDICATIONS FOR USE

Instrumentation supplied by Cartiva, Inc is indicated for use with implantable medical device products manufactured by Cartiva, Inc.

CONTRAINDICATIONS

Instrumentation supplied by Cartiva, Inc. is not designed, sold or intended for use other than as indicated.

WARNINGS & PRECAUTIONS

- Failure to properly clean instruments prior to sterilization may lead to inadequate sterilization.
- Surgical instruments are used with or on patients who may harbor both recognized and unrecognized infections. To prevent the spread of infection, all reusable instruments must be thoroughly cleaned and sterilized prior to initial use and after each patient use.
- Instruments may have sharp edges or features. Users and reprocessors must be cautious when handling instruments.

Limitations on reprocessing

- Repeated processing, according to these instructions, has minimal effect on and should not compromise the performance of reusable Cartiva instruments. End of life is normally determined by wear and damage due to use.

Damage Inspection

- Inspect the instruments for damage, wear, and corrosion at all stages of handling.
- Cutting edges should be free of nicks and present a continuous edge.
- Check instruments with long slender features for distortion.
- If damage is detected, do not use instrument but consult Cartiva, Inc. for guidance.

SPECIAL INSTRUCTIONS

Transmissible Spongiform Encephalopathy Agents

- It is outside the scope of this document to describe in detail the precautions that should be taken for Transmissible Spongiform Encephalopathy agents.
- The agents for transmission of Creutzfeldt-Jakob disease (CJD) are believed to be resistant to normal processing methods of disinfection and sterilization. Methods of decontamination and sterilization outlined below may not be appropriate where CJD transmission is a risk.
- Refer to the World Health Organization guidelines for a detailed listing of appropriate decontamination methods.

INSTRUMENT DESCRIPTION

This document pertains to the following instruments supplied by Cartiva, Inc.:

Non-Sterile Instrumentation

Part Description	Instrumentation REF	Classification
Drill Bit (Fabricated from 455 or 17-4 H900 Stainless Steel)	MTD-06	Reusable
	MTD-08	
	MTD-10	
Introducer (Fabricated from 17-4 H900 Stainless Steel)	INT-06	Reusable
	INT-08	
	INT-10	
Placer (Fabricated from 17-4 H900 Stainless Steel)	PLC-06	Reusable
	PLC-08	
	PLC-10	

Note: All drill bits (part numbers MTD-##) are designed for use with drills having a chuck size of at least 0.25". The drill bits are not compatible with a 6 mm chuck.

PACKAGING

The Cartiva SCI reusable sterilization tray and associated reusable surgical instruments are supplied non-sterile and must be cleaned and sterilized prior to use according to the instructions in this document. The reusable instruments and tray are shipped and stored in packaging that is labeled according to its contents. Store the sterilization tray in normal hospital environmental conditions. Store the instruments in the original packaging. Do not remove a reusable instrument from the packaging until it is ready to be placed in the sterilization tray.

CLEANING & STERILIZATION INSTRUCTIONS

Post-use

- Remove excess soil with disposable non-shedding wipe.
- Instruments should be covered with a damp cloth to prevent drying of soil prior to cleaning.

Containment and transportation

- Observe universal precautions for handling contaminated/biohazardous materials.
- Instruments should be cleaned within 30 minutes of use to minimize the potential for drying prior to cleaning.

Cleaning

Preparation for cleaning

- No assembly/disassembly of Cartiva instruments is required.
- For initial and subsequent uses, follow all cleaning and sterilization instructions.
- Cleaning agents with chlorine or chloride as the active ingredient are corrosive to stainless steel and must not be used. Acidic cleaning agents should be avoided.
- Saline solution has a corrosive effect on stainless steel and should not be used to rinse, soak, or clean instruments.

Manual Cleaning

- Prepare a neutral pH or nearly neutral pH enzymatic detergent at the use-dilution and temperature recommended by the agent's manufacturer.
- Submerge the instruments in enzymatic detergent and soak for 20 minutes.
- While submerged in enzymatic detergent, scrub each instrument with a soft-bristled brush, paying special attention to areas where debris might accumulate. Lumens and crevices should be cleaned with a long, narrow, soft-bristled brush. Avoid any harsh materials or cleaning motions that can scratch the surface of the instruments.
- Remove the instruments from the enzymatic detergent and rinse each instrument thoroughly in purified water (such as distilled or deionized water) for a minimum of 3 minutes. Thoroughly flush lumens and other difficult to reach areas.
- Sonicate instruments for a minimum of 10 minutes in an ultrasonic cleaner containing fresh enzymatic detergent, preferably at 45-50 kHz (according to the ultrasonic unit's directions).
- Remove the instruments from the enzymatic detergent and rinse each instrument thoroughly with purified water (such as distilled or deionized water) for at least 3 minutes and until there is no sign of soil in the rinse stream. Thoroughly flush lumens and other difficult to reach areas.

Verifying Cleaning

- Check instruments for visible soil. All exterior surfaces as well as inner lumens should be inspected.
- Repeat cleaning if soil is visible and re-inspect.

Disinfection

- Disinfection is only acceptable as an adjunct to full sterilization for reusable surgical instruments.
- Disinfectant solution Cidex® or equivalent may be used in accordance with solution supplier's instructions. Instruments should be thoroughly rinsed in purified water (such as distilled or deionized water) following disinfection.

Drying

- Instruments with inner lumens should be agitated or positioned so that liquid inside the lumens may drain.
- Dry the exterior of the instruments with a clean, disposable, non-shedding wipe.

Automated Cleaning

Manual Pre-Cleaning

- Prepare an enzymatic cleaner per manufacturer's directions. Soak all instruments in the enzymatic cleaning solution for a minimum of five (5) minutes. After five (5) minutes of soak time, remove gross soil using a soft bristled brush, paying special attention to areas where debris might accumulate. Lumens and crevices should be cleaned with a long, narrow, soft-bristled brush. Flush the inside of lumens using a syringe or pipette filled with the prepared cleaning solution for a minimum of three (3) times.
- Rinse each soiled instrument under running cold tap water for a minimum of one (1) minute. Thoroughly flush lumens and other difficult to reach areas.

Automated Process

- Load the instruments in a washer disinfector so that the lumens can drain.
- Using a validated washer disinfector and an alkaline cleaning agent (8-11 pH range) intended for use in an automated cleaning process, use the minimum cycle parameter set points below.

Cycle	Time (minutes:seconds)	Minimum Temperature	Type of Detergent/ Water
Pre-Cleaning	2:00	Cold	Tap
Cleaning	10:00	Heated 50°C - 60°C	Alkaline detergent (per the manufacturer's instructions) and tap water
Rinse 1	2:00	Cold	Tap
Rinse 2	1:00	Cold	Purified Water*
Dry	25:00	Heated (90°C)	N/A

* Purified water for the final rinse may be distilled, deionized, or reverse osmosis water

- Visually inspect the instruments for remaining soil in a well-lit area; no visible soil should be left on any instrument surfaces.
- If instruments are still wet after automated cleaning cycle, thoroughly dry the instruments using a clean lint-free cloth. If needed, use filtered pressurized air to aid in drying.
- The instruments withstand steam exposure up to 137ºC and, thus, may be thermally disinfected.

Cleaning of Reusable Sterilization Tray

The instrument sterilization tray provided with reusable instrumentation should be cleaned, sterilized and inspected prior use in accordance with the tray's Instructions for Use.

Warnings

- Do not stack trays on top of one another. Be sure that ventilation holes are not obstructed, and that mats are correctly installed. For effective sterilization trays must have adequate steam circulation around all surfaces. They must also be placed upright on shelves for proper ventilation. Condensation can pool on non-absorbent surfaces. Do not place trays on their sides or at vertical angles in chamber, in order to ensure that proper drainage can occur during the cycle.
- Small baskets, trays, or other accessories with covers or lids should only be used in trays specifically designed and labeled for the purpose. Do not overload trays. Overloading may inhibit steam flow, cause excessive drying times, and make trays too heavy to safely handle. Load and sterilize instruments in trays in accordance with the instructions provided within this IFU.

Sterilization

Packaging for Sterilization

Instruments may be loaded into dedicated instrument trays or general-purpose sterilization trays. The maximum load configuration, regardless of instrument size, is as follows:

- 1 x Drill Bit (MTD-##)
- 1 x Introducer (INT-##)
- 1 x Placer (PLC-##)

Use standard medical-grade steam sterilization wrap to double-wrap the tray.

Recommended Sterilization Parameters

- Steam sterilize using one of the three following steam cycles. Each has been found to demonstrate a sterilization assurance level (SAL) of 10^{-6} for the maximum load configurations described above (AAMI TIR12:2004):

Cycle Number	1	2	3
Autoclave Type	**Gravity**	**Pre-Vacuum**	**Pre-Vacuum**
Sterilization Temperature	270°F/132°C (+5°F / +3°C)	270°F/132°C (+5°F / +3°C)	273°F/134°C (+5°F / +3°C)
Exposure Time	25 minutes	4 minutes	3 minutes
Minimum Drying Time	30 minutes	20 minutes	20 minutes

- Sterilizers vary in design and performance characteristics, so cycle parameters should be verified against the sterilizer manufacturer's instructions for the specific sterilizer and load configuration being used.

- When sterilizing multiple instruments in one steam sterilization cycle, ensure that the sterilizer manufacturer's maximum load is not exceeded.
- Drying time may vary according to load size (larger loads require longer drying times).
- Instruments must be adequately cooled after removal from the sterilizer. Do not touch instruments during the cooling process.

STORAGE

- Sterilized, packaged instruments should be stored in a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin, and temperature/humidity extremes.
- Sterilized instrument packages should be examined closely prior to opening to ensure that there has been no loss of package integrity.

MAINTENANCE

- No lubrication is needed.
- Discard blunt, damaged, severely corroded or severely discolored instruments.

The instructions provided above have been validated by Cartiva, Inc. as being capable of preparing non-sterile instruments for initial use or re-use. It is the responsibility of the reprocessor to ensure that reprocessing is performed using the appropriate equipment and materials, and that personnel in the reprocessing facility have been adequately trained in order to achieve the desired result. This normally requires validation and routine monitoring of the process. Any deviation by the reprocessor from these instructions should be properly evaluated for effectiveness to avoid potential adverse consequences.

For the most current Cartiva® Synthetic Cartilage Implant product information, including surgical technique and scientific publications, please visit our website at www.cartiva.net.

References

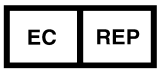
1. AAMI TIR12:2004. Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers
2. ISO 17664: 2004. Sterilization of medical devices —Information to be provided by the manufacturer for the processing of resterilizable medical devices
3. WHO/DCS/CSR/APH/2000.3, WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies, March 1999.

CONTACT INFORMATION

	Cartiva, Inc. 6120 Windward Parkway, Suite 220 Alpharetta, GA 30005, USA +1-770-754-3800
Australian Sponsor	Stryker Australia Pty Ltd 8 Herbert Street, St Leonards NSW 2065 T: 61 2 9467 1000

SYMBOLS USED IN LABELING

	Do not re-use
	Consult instructions for use
	Non-sterile
	Non-pyrogenic
	Upper limit of temperature
	Use-by date
	Do not use if package is damaged
	Medical device

	CE mark and identification number of Notified Body
	Catalogue number
	Batch code
	Date of manufacture
	Manufacturer
	Sterilized using irradiation
	Authorized representative in the European Community