**INSTRUMENT DESCRIPTION**

The Cartiva SCI Instrumentation supplied by Cartiva, Inc. is not designed, sold or intended for use other than as indicated within the Cartiva SCI Instructions for Use. The reusable Cartiva SCI instruments are constructed of surgical grade stainless steel types 17-4SS H900 and 455SS H900 (as referenced in ASTM F899 “Wrought Stainless Steel for Surgical Instruments”).

**INDICATIONS FOR USE**

Orthopedic surgical instrumentation supplied by Cartiva, Inc. is indicated for use in the press-fit fixation of the implantable medical device products manufactured by Cartiva, Inc. The reusable instruments are manufactured in two sizes, 8mm and 10mm, and are intended for the implantation of the 8mm and 10mm Cartiva SCI into the first metatarsal head joint.

For additional information on the Cartiva implants, see instructions for use provided with these.

**CONTRAINDICATIONS**

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

**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 the Cartiva SCI device has been validated for use with surgical instrumentation distributed by Cartiva, Inc. The non-sterile Cartiva SCI Instruments have been validated for their intended function and use with a cannulated drill 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 to 1.5mm) with the surrounding cartilage:

<table>
<thead>
<tr>
<th>Part Description</th>
<th>Instrumentation Reference</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drill Bit (Fabricated from 455 or 17-4 H900 Stainless Steel)</td>
<td>MTD-08</td>
<td>Reusable</td>
</tr>
</tbody>
</table>

**CLEANING OF REUSABLE INSTRUMENTATION**

The reusable instrumentation must be sterilized by the user prior to use in surgery.

**Precautions**

- Failure to properly clean reusable instruments prior to sterilization may lead to inadequate sterilization.
- Surgical instruments are used with or on subjects 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 reproprocessors 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 SCI instruments. End of life is normally determined by wear and damage due to use.

- In addition to the Cartiva SCI Instrumentation that is labeled for re-use, Cartiva, Inc. provides single-use placement guide pins for use during the Cartiva SCI implantation procedure. Re-use of the single-use placement guide pins or disposable instrumentation is strictly prohibited. The material properties and reliability of these devices in a multi-use scenario have not been explicitly tested or demonstrated. Re-use of a single-use instrument could result in improper device placement (depth, alignment, etc.) and undesired clinical outcomes.
- Placement Guide Pins must be discarded after one use.

**Damage Inspection**

- Inspect the reusable 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.

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) such 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 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 1.5mm) in the implant site.

**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.

**HANDLING**

All instruments should be treated with care. Improper use or handling may lead to damage and/or possible malfunction. Instruments should be checked to ensure that they are in working order prior to surgery. All instruments should be inspected prior to use and at all stages of handling to ensure that there is no unacceptable deterioration such as damage, wear, nicks or corrosion. Cutting edges should be free of nicks and present a continuous edge. Long slender instruments should be inspected for any distortion. If any damage is detected, do not use the instrumentation. Non-working or damaged instruments should be returned to Cartiva, Inc., USA.

**CLEANING OF REUSABLE INSTRUMENTATION**

The reusable instrumentation must be sterilized by the user prior to use in surgery.

**Precautions**

- Failure to properly clean reusable instruments prior to sterilization may lead to inadequate sterilization.
- Surgical instruments are used with or on subjects 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 reproprocessors 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 SCI instruments. End of life is normally determined by wear and damage due to use.

- In addition to the Cartiva SCI Instrumentation that is labeled for re-use, Cartiva, Inc. provides single-use placement guide pins for use during the Cartiva SCI implantation procedure. Re-use of the single-use placement guide pins or disposable instrumentation is strictly prohibited. The material properties and reliability of these devices in a multi-use scenario have not been explicitly tested or demonstrated. Re-use of a single-use instrument could result in improper device placement (depth, alignment, etc.) and undesired clinical outcomes.
- Placement Guide Pins must be discarded after one use.

**Damage Inspection**

- Inspect the reusable 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.

The REUSABLE instruments are provided non-sterile and require sterilization prior to use.

Access the affected joint using standard surgical technique. Care should be taken to avoid nerve damage along the dorsal-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 dorsal 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 slightly asymmetrical so as to be placed over the worst area of arthritic involvement on the metatarsal head. Cartiva requires a minimum of 2mm of surrounding bone stock. Insert the Placement Guide Pin into the defect.

Select the appropriate Drill Bit (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 Placement 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.

Cartiva, Inc. Document #L20-0702 Rev. A
MANUAL CLEANING INSTRUCTIONS
Automated cleaning may not be effective at removing debris from inner lumens or crevices and is not validated or recommended.

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.

Preparation for Cleaning
- No assembly/disassembly of Cartiva SCI instruments is required.
- For initial and subsequent uses, follow all cleaning and sterilization instructions.
- Prepare a neutral pH or nearly neutral pH enzymatic detergent at the use-dilution and temperature recommended by the agent’s manufacturer.
- Cleaning agents with chlorine or chloride as the active ingredient are corrosive to stainless steel and must not be used. Acetic 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.

CLEANING OF REUSABLE TRAY
The reusable sterilization tray provided with reusable instrumentation should be cleaned, sterilized and inspected prior use in accordance with the tray’s Instructions for Use.

Verifying Cleaning
- Check instruments for visible soil. All exterior surfaces as well as inner lumens should be inspected to ensure no visible contamination.
- Repeat cleaning if soil or contamination is visible and re-inspect.

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.

Sterilization Parameters
Steam-sterilize using one of the two validated steam cycles listed below. Each has been found to demonstrate a sterilization assurance level (SAL) of 10^6 for the maximum load configurations described above (AAMI TIR12):

<table>
<thead>
<tr>
<th>Gravity</th>
<th>Pre-Vacuum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterilization Temperature</td>
<td>270°F / 132°C (+5°F / +3°C)</td>
</tr>
<tr>
<td>Exposure Time</td>
<td>25 minutes</td>
</tr>
<tr>
<td>Minimum Drying Time</td>
<td>30 minutes</td>
</tr>
</tbody>
</table>

*1 Sterilization Validation Temperature Range

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 reusable 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. Instrument packages should be examined closely prior to opening to ensure that there has been no loss of package integrity.

PRODUCT COMPLAINTS
Any health care professional (e.g., customer or user of this system), who has complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify Cartiva, Inc. USA. Further, if any of the implanted system ever “malfunctions” (i.e. does not meet any of its performance specifications or otherwise does not perform as intended) or may have caused or contributed to the death or serious injury of a patient, Cartiva, Inc. should be notified immediately by telephone, fax or written correspondence. When filing a complaint, please provide the device size, part number, lot number(s), your name and address, and the nature of the complaint. Complaints may also be reported directly to Medwatch at http://www.fda.gov/medwatch.

WARRANTY
The manufacturer does not take responsibility for any effects on safety, reliability or performance of the product if the product is not used in conformity with the instructions for use. Limited warranty and disclaimer: Cartiva, Inc. products are sold with a limited warranty referred to the original purchaser against defects in workmanship and materials. To the maximum extent permitted by applicable law any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

CAUTION
Federal (U.S.A.) Law Restricts this Device to Sale by or on the order of a Physician.

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

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<table>
<thead>
<tr>
<th>SYMBOL</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Symbol" /></td>
<td>Do not re-use</td>
</tr>
<tr>
<td><img src="image" alt="Symbol" /></td>
<td>Consult instructions for use on this website</td>
</tr>
<tr>
<td><img src="image" alt="Symbol" /></td>
<td>Non-sterile</td>
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<tr>
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<tr>
<td><img src="image" alt="Symbol" /></td>
<td>Date of manufacture</td>
</tr>
<tr>
<td><img src="image" alt="Symbol" /></td>
<td>Medical device</td>
</tr>
<tr>
<td><img src="image" alt="Symbol" /></td>
<td>CE mark. The product meets the essential requirements of Medical Device Directive 93/42 EEC.</td>
</tr>
<tr>
<td><img src="image" alt="Symbol" /></td>
<td>Manufacturer</td>
</tr>
</tbody>
</table>