



CARTIVA[®] SL

SURGICAL IMPLANTATION TECHNIQUE

Excerpt from Cartiva SL Synthetic Cartilage Implant (SCI) Instructions for Use

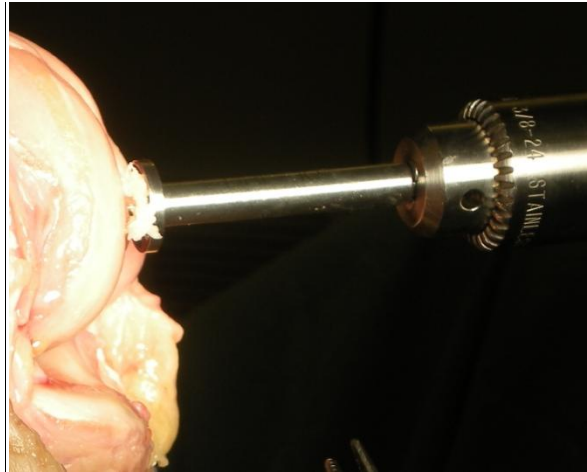
Cartiva[®] Synthetic Cartilage Implant – Surgical Implantation Technique

Warning: Use ONLY Cartiva SL Instruments to prepare the implant site

1. Confirm the size of the lesion using the SL Placer and ensure that the required Cartiva SL implant is available to complete the repair.
2. Position the concave end of an SL Placer against the defective area. With the SL Placer centered over the defective area, insert a Guide Pin through the SL Placer and drill it into the subchondral bone.



3. Secure the Counterbore Drill Bit within the drill chuck. Place the Counterbore Drill Bit over the Guide Pin and drill until the stop flange reaches the level of the cartilage surface. Withdraw the Counterbore Drill Bit from the implant cavity.



4. Remove the Counterbore Drill Bit from the drill chuck and replace with the Taper Counterbore Shaper. Place the Taper Counterbore Shaper over the Guide Pin, ensure the shaping blade is retracted. Advance the Taper Counterbore Shaper until the stop flange reaches the level of the articular surface. Deploy the taper shaping blade by pulling back the actuator sleeve. Power the drill for 3 – 5 seconds keeping the stop flange in gentle contact with the surrounding articular surface. Allow the Taper Counterbore Shaper to come to a full stop, retract the taper shaping blade by pushing the actuator sleeve forward, and then withdraw the Taper Counterbore Shaper from the implant cavity.



Taper Counterbore Shaper (shaping blade retracted)



Taper Counterbore Shaper (shaping blade deployed)

The Taper Counterbore Shaper that produces the required taper within the implant cavity is manually operated, and must be deployed and retracted without removal of shaper from the implant cavity. Damage to the implant cavity may occur if the shaper is withdrawn with the shaping blade deployed. Always insert or withdraw the Taper Counterbore Shaper with the shaping feature stowed (actuator slide positioned forward – toward the cutter head).

5. Remove the Guide Pin from the implant cavity. If necessary, remove any cartilage and/or bone debris from the recipient implant site.

6. Remove a Cartiva SL SCI from its packaging and insert the flat end of the implant (rounded shoulder anterior) into the wide end of an SL Introducer.

7. Rest the distal end of the SL Introducer on a flat, non-shedding, sterile surface and slowly advance the implant to the distal end of the SL Introducer using the SL Placer, taking care to not eject the device from the distal end.

8. Place the distal end of the SL Introducer into the opening of the target implant cavity. Using a two handed technique, advance the Cartiva SL SCI into the implant cavity using the SL Placer. Remove the SL Introducer and SL Placer.

9. Confirm that the final placement of implant is tight within the implant cavity. The articulating surface of the implant should be flush with the surrounding cartilage.