M6-C Artificial Cervical Disc Chisel-Over-Trial

Surgical Technique
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The M6-C Artificial Cervical Disc

The M6-C artificial cervical disc is designed to replicate the anatomic structure and biomechanical performance of a natural disc. Its innovative design incorporates an artificial nucleus to allow axial compression and a woven fiber annulus for controlled range of motion in all six degrees of freedom. The following surgical technique describes the steps for the implantation of the M6-C Artificial Cervical Disc.

The M6-C Artificial Cervical Disc System is intended to be used only by surgeons with training particular to the implant system, cervical spine surgery and related surgical techniques and biomechanical principles of the spine and spine arthroplasty.

CAUTION: Read and understand the M6-C artificial cervical disc system Instructions for Use prior to use.
The M6-C System

M6-C Artificial Disc Heights & Footprint Sizes

M6-C Artificial Disc Heights & Footprint Sizes

Posterior

Anterior

M6-C COT Instruments

SpinaKinetics
Motion for Life
Patient Positioning

• Position the spine in a neutral position and support with a soft roll. Confirm via fluoroscopy that the spine is not in extension, flexion, or rotation.

• Secure or tape the head to prevent unwanted movement. The shoulders may be taped and pulled down for better visualization of the lower cervical spine.
**Approach**

Using either a right or left-side approach and standard anterior cervical technique, dissect down to the treatment level(s), and confirm the desired disc space with fluoroscopy. Use careful dissection to preserve the longus colli muscles for use as an initial midline reference.

**Midline Identification and Placement of Retainer Pins**

Using AP and lateral fluoroscopic guidance, place the Cervical Retainer Pins into the adjacent vertebrae. Each pin should be inserted parallel to its respective endplate and in the midline. Select a Pin of sufficient length to obtain good bone purchase.

**NOTE:** If properly placed, the Cervical Retainer Pins can provide visual reference for midline and disc space trajectory for subsequent steps during implantation of the M6-C disc.

**WARNING:** Do not allow the Retainer Pins to progress beyond the posterior vertebral cortical rim. Allowing the Retainer Pins to progress beyond the posterior border of the vertebrae may result in patient injury.

**Discectomy and Decompression**

Perform discectomy to the posterior disc space, the lateral annulus and uncovertebral joints. A total, symmetrical decompression should be completed.
Vertebral Endplate Preparation

- Use rongeurs, punches and/or drills to remove anterior and posterior osteophytes as needed.
- Use curettes or similar instruments to remove the cartilaginous endplates.

**NOTE:** Take care to preserve cortical bone and maintain endplate angles.

**CAUTION:** Excessive removal of endplate cortical bone may result in sub-optimal outcomes.

Intervertebral Distraction

- With fluoroscopic guidance, use the Intervertebral Distractor to restore the desired height and to mobilize the treatment disc space as needed. (Fig. A, B)
- Use the Cervical Retainer to maintain the desired disc space height.

**NOTE:** To prevent abnormal disc space angles, do not use the Cervical Retainer alone to gain disc space height.

**CAUTION:** Take care not to over-distract the disc space.

**WARNING:** Do not allow the Intervertebral Distractor to progress more posteriorly than the posterior border of the vertebrae. Allowing the Intervertebral Distractor to progress beyond the posterior border of the vertebrae may result in patient injury.

Re-assessment of Midline

Visualize the medial aspect of the uncovertebral joints. Confirm that the Retainer Pins are in the midline as indicated by the point midway between the medial uncinates. If necessary, mark a corrected midline reference on the anterior vertebral bodies. (Fig. C)
Footprint Sizing

- With fluoroscopic guidance and visualization, use the Footprint Template to determine the correct size (Medium, Medium Long, Large, Large Long) M6-C Artificial Cervical Disc footprint. (Fig. A)

- Lay the Template onto the prepared vertebral endplates and determine which size provides maximum endplate coverage anterior to posterior. The posterior and anterior edges of the Template should come within 1-2mm of the vertebral borders. (Fig. B)

- The Template should fit within the medial aspect of the uncovertebral joints, with good vertebral endplate contact.

- Slight symmetrical resection of the medial borders of the uncinate processes may need to be performed to allow the Footprint Template to fit correctly.

WARNING: Take care not to allow the Template to go beyond the posterior border of the vertebral bodies. Allowing the Template to go beyond the posterior border of the vertebral bodies may result in patient injury.

Using the Chisel-Over-Trial Adjustable Stop

- Assemble the Universal Handle according to the instructions. (Fig. C) (Fig. D)

- Follow the instructions within this Technique Manual regarding choosing the correct size Trial, and how to orient the Trial within the disc space.

  1. Prior to attaching the Trial to the Universal Handle, dial the Stop back so that the Indicator Mark on the Stop Assembly is behind the first Indicator Lines on the Universal Handle by rotating the Stop Adjustor Knob clockwise.

  2. Attach the Trial to the Handle. If the Trial is difficult to completely seat, or binds against the Stop Assembly, rotate the Stop Adjustor Knob clockwise to move the Stop further backwards.

  3. Once the Trial has been completely attached, the Stop may be oriented forward by rotating the Stop Adjustor Knob counterclockwise.

  4. Once the Trial is within the disc space, rotating the Stop Adjustor Knob clockwise will move the Stop backwards to allow the Trial to be advanced further into the disc space.

  5. Always use fluoroscopy when advancing the Trial.

  6. Prior to insertion of the Chisel Blades, the Stop must be firmly seated against the anterior vertebral body.
Trial Assessment: Disc Height

- Attach the appropriate (Medium, Medium Long, Large, Large Long) 6mm Trial Head to the Universal Handle by rotating the Knob clockwise.

- Align the Midline Mark of the Trial Head to the midline. The Stop may be oriented either caudal or cephalad.

- Under close fluoroscopic guidance, insert the Trial Head into the disc space with light tapping. Rotate the Stop Adjuster Knob clockwise to move the Stop backwards and allow for more posterior placement of the Trial Head as needed. (Fig. A)

- Relieve external distraction so that the vertebral endplates and Trial are in firm contact.

- Stop the progress when the Trial is approximately halfway into the disc space. Use the Center Alignment Port (CAP™) to align the C-arm on plane to the disc space and the Trial Head. Once the C-arm is on plane, the CAP will become a complete circle. Continue Trial Head Advancement while observing the progress on lateral fluoroscopy, until the posterior edge of the Trial Head is within 1-2mm of the posterior vertebral border. (Fig. B)

- With the Trial in the desired position, adjust the Stop so it is in firm contact with the anterior vertebral body. (Fig. C)

  NOTE: The Trial Head should be positioned so that it rests on cortical bone.

- With the 6mm Trial Head in place, observe the treatment level disc space height, facet joints and spinous process and compare to adjacent levels. There should be good correlation of adjacent level height with the index level and no over-distraction of the disc space.

- If additional height is desired, repeat the above steps using the 7mm Trial.

  NOTE: External distraction upon insertion of Trial Head may result in an over estimate of actual disc height.

WARNING: Fluoroscopic visualization must be maintained during the placement of the Trial Head. Do not allow the Trial Head to go beyond the posterior border of the vertebral bodies. Failure to visualize the Trial Head during this step could result in patient injury.

WARNING: Placement of the Trial Head beyond the posterior
Trial Assessment: Midline Location

- Remove the Universal Handle from the Trial Head by rotating the Knob counter-clockwise. (Fig. A)
- Place the C-arm into A/P position and align to the spine using the spinous processes and lateral vertebral anatomy as a rotational reference. The Center Alignment Port (CAP) will allow quick angular alignment of the C-arm to the plane of the disc space.
- Once the C-arm is aligned to the spine and disc space, use fluoroscopy to visualize the Trial in relation to the uncovertebral joints and confirm that it is in the midline. (Fig. B) (Fig. C)
- Make any necessary adjustments to the Trial Head with the C-arm in the A/P position.

Realign C-arm to Lateral view

Return the C-arm to the lateral position and re-align to the lateral CAP. If the Trial was repositioned for midline location, re-confirm the position in the sagittal plane. Lock the C-arm in this position. Use this C-arm position for the chisel and implant steps.
Keel Track Cutting

- Confirm that the Stop makes firm contact with the anterior vertebral body.
- Remove the Knob from the Universal Handle. (Fig. A)
- Select the correct Chisel size based on the height of the Trial Head (6mm or 7mm).
- Confirm that there is no additional external distraction applied.
- Slide the first Chisel through the body of the Universal Handle. Carefully tap the Chisel into the disc space until the Chisel reaches the end of the Trial Head. (Fig. B)
- Do not remove the first chisel.
- Insert the second Chisel and repeat the previous step. (Fig. C) (Fig. D)
- Fluoroscopic imaging must be maintained during advancement of the Chisel.
- Remove the Chisels, then the Trial using the Slide Hammer.

NOTE: The final position of the Chisel will determine the position of the M6-C disc. Do not allow the Chisel and Trial assembly to progress beyond the desired location of the M6-C disc by ensuring that the Stop is firmly seated against anterior bone prior to introducing the Chisels.

WARNING: Allowing the Chisel and Trial assembly to progress beyond the posterior border of the vertebral bodies may result in patient injury.

WARNING: Fluoroscopic visualization must be maintained during the advancement of the Chisel. Do not allow the Chisel and Trial assembly to go beyond the posterior border of the vertebral bodies. Failure to visualize the Chisel during this step could result in patient injury.
Loading the M6-C Cervical Disc

- With the Chisels removed, replace the Knob on the Universal Handle. Remove the Trial Head from the Universal Handle by rotating the Knob counter-clockwise.
- Select the appropriate Inserter Head and attach it to the Universal Handle by rotating the Knob clockwise.
- Advance the Inserter onto the disc.
- Flip the toggle to release the disc from the Packaging Clip.
- The M6-C is now loaded and ready to insert.

**NOTE:** The anterior edge of the Implant endplate must be flush against the Inserter.
M6-C Cervical Disc Insertion

- Confirm that no additional external distraction is in place, and that the Stop position has not changed from the Trial and Chiseling steps.

- Align the center keel of the M6-C to the middle keel track cut by the Chisel. Orient the handle of the Universal Handle to the trajectory of the disc space as viewed on lateral plane fluoroscopy.

- Using fluoroscopic guidance, carefully tap the Universal Handle/M6-C into the disc space keeping the keels aligned to the cut keel tracks. (Fig. A)

- Continue carefully advancing the Universal Handle/M6-C while observing the progress via fluoroscopy until the posterior edge of the disc reaches the desired location.

- Verify that the M6-C is at the desired posterior position before removing the Universal Handle with the Inserter Head. Remove the Inserter Head from the M6-C while using a gentle right-to-left and pulling motion.

- Once the Inserter Head is removed, make a final assessment of positioning via lateral and A/P fluoroscopy.

- **Closing:** Close the wound following standard practices.

**NOTE:** If the Inserter Head must be re-attached for additional posterior placement, make sure that both upper and lower M6-C endplates are in good contact with the face of the Inserter. A slight amount of external distraction may be necessary to completely reattach the Inserter Head. Release the external distraction prior to attempting further positioning.

**NOTE:** The M6-C cannot be placed more posteriorly than the final posterior position obtained by the Chisel.

**CAUTION:** The M6-C cannot be repositioned anteriorly. Take care not to place the M6-C disc beyond the desired posterior position.

**WARNING:** Fluoroscopic visualization must be maintained during the insertion. Do not allow the M6-C to go beyond the posterior border of the vertebral bodies. Failure to visualize the Implant during this step could result in patient injury.

**WARNING:** Allowing the M6-C disc to progress beyond the posterior border of the vertebral bodies may result in patient injury.
M6-C Multiple Level Technique

• Follow the steps as described for patient positioning.
• Insert the Cervical Retainer Pins centrally within the vertebral bodies so that they will not interfere with the keels of the M6-C discs above or below. Follow the steps described for placement of the Cervical Retainer Pins.
• Depending on the severity of the involved levels, the surgeon may find it advantageous to perform discectomy and decompression on both levels prior to insertion of the first M6-C disc.
• Follow all steps for height restoration, disc space mobilization, endplate preparation, determination of footprint and disc height sizing for each level.
• Follow all steps for positioning the Trial, cutting keel tracks with the Chisel, and insertion of the M6-C disc.
M6-C Cervical Disc Explantation

If the M6-C Artificial Cervical Disc needs to be removed, the following steps should be utilized. After the removal of the Implant, the surgeon’s clinical judgment will dictate the proper method for stabilizing the disc space.

- An anterior approach is used to access the involved level.
- Place the Cervical Retainer Pins into the adjacent vertebrae. Each pin should be inserted parallel to its respective endplate.
- Introduce gentle external distraction across the interspace.
- Cut through the outer sheath and artificial annulus of the M6-C disc to expose the polymer nucleus.
- Use rongeurs or forceps to remove the polymer nucleus.
- Carefully detach the titanium endplates from the vertebral endplates using elevators or other suitable instruments.
- Irrigate and suction to remove potential debris.