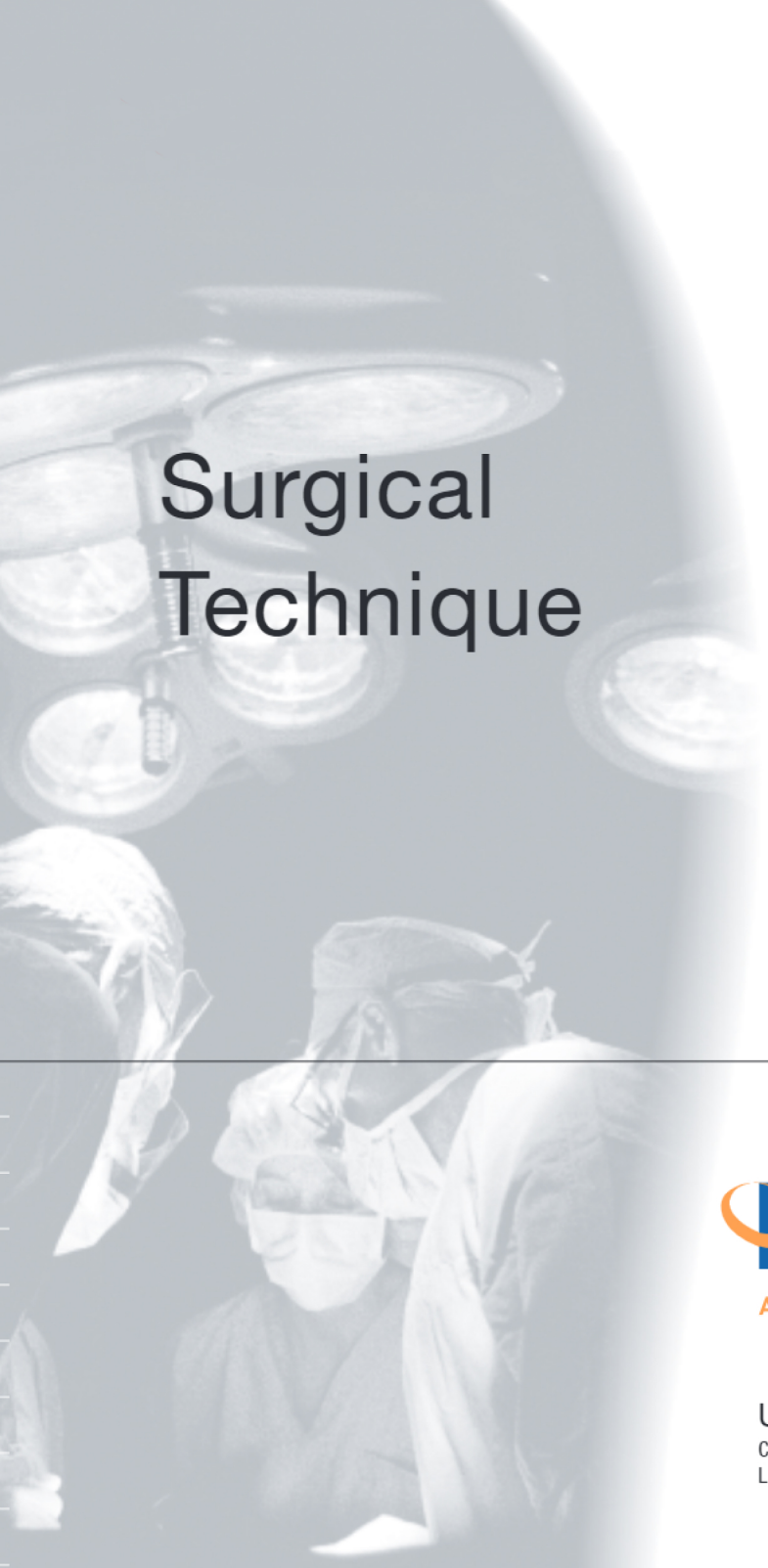
CENTINEL SPINE®

Surgical Technique



DISCOVER™

ARTIFICIAL CERVICAL DISC

U.S. Investigational Device

CAUTION: Investigational Device.
Limited by Federal (or United States) law to investigational use.

CONTENTS

DISCOVER™

ARTIFICIAL CERVICAL DISC

INTRODUCTION

PATIENT SELECTION

INDICATIONS FOR USE

The DISCOVER™ Artificial Cervical Disc is indicated for the treatment of symptomatic cervical degenerative disc disease at one level between C3 and C7 presenting with:

- *Neck or arm (radicular) pain;*
- *A functional/neurological deficit with at least one of the following conditions confirmed by imaging (CT, MRI or Xrays):*

  - Herniated nucleus pulposus;

  - Spondylosis (defined by the presence of osteophytes); and/or

  - Loss of disc height.

PRE-OPERATIVE PLANNING

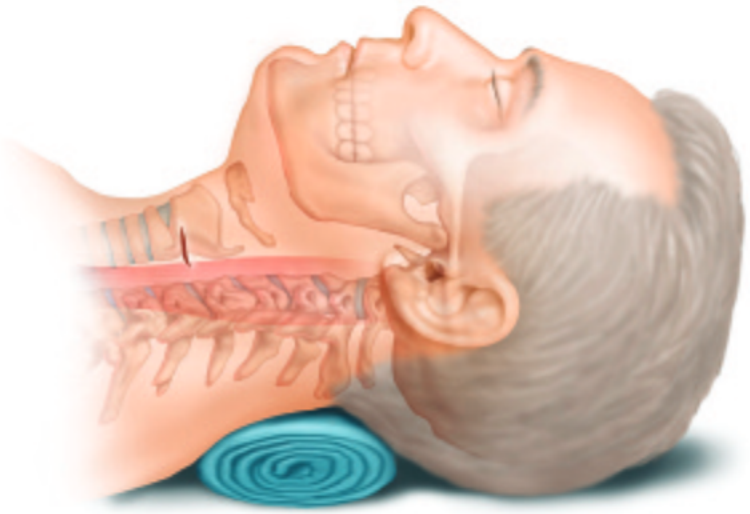
Successful clinical outcomes with the DISCOVER Artificial Cervical Disc begin with a thorough pre-operative plan. Prior to performing any artificial disc surgery, a review of pre-operative patient imaging is necessary to identify any contraindications to artificial disc surgery.

DISCOVER
Artificial Cervical Disc
ACCESS

STEP 1 – PATIENT POSITIONING

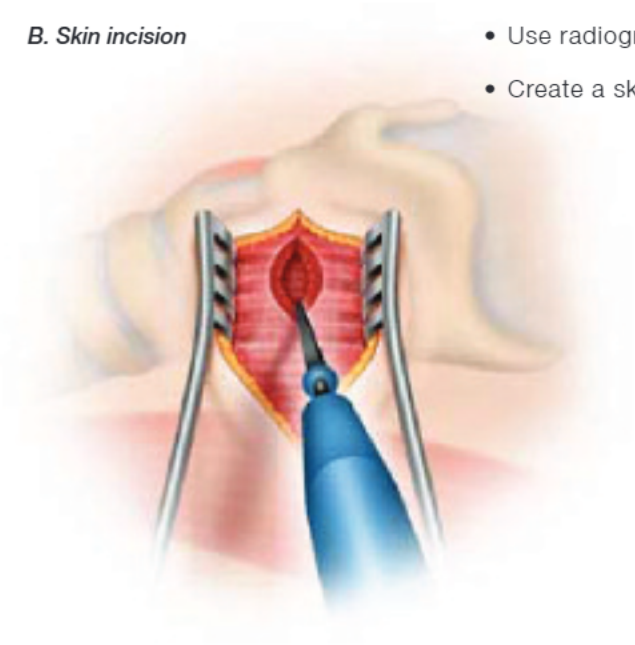
- Position the patient supine and drape according to standard operating room protocol.
- The patient should be positioned such that the neck and the head are in a true neutral sagittal position with the head not turned to the right or left.
- The mid-cervical spine should be supported to maintain normal lordosis. The support, which may simply be a firm cotton/wool roll, is necessary to provide resistance during impaction and placement of the implant and Trials.
- In order to ensure neutral patient position is maintained throughout the procedure, use appropriate means of stabilization.

A. Position patient



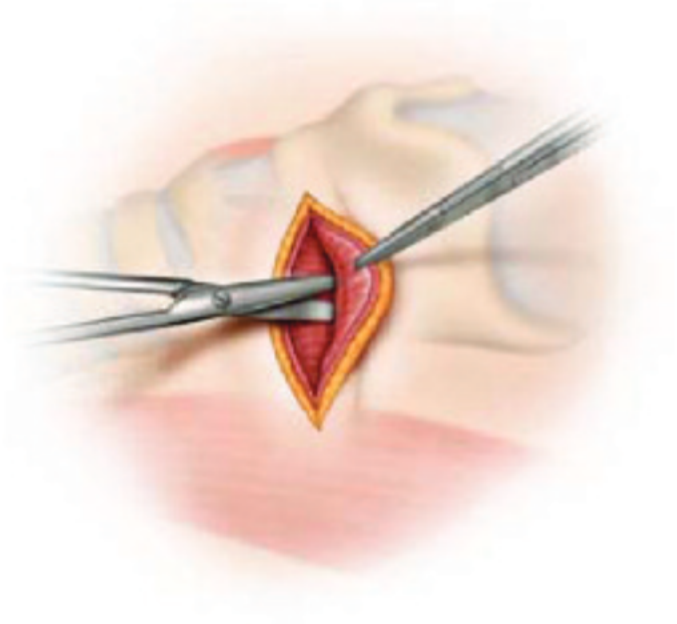
STEP 1 – PATIENT POSITIONING (continued)

B. Skin incision



- Use radiographic imaging to confirm the targeted anatomy.
- Create a skin incision over the appropriate disc space.

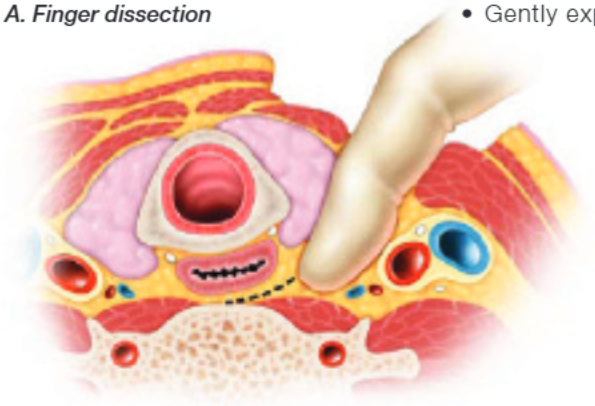
C. Incise the platysma



- Undermine and then incise the platysma.

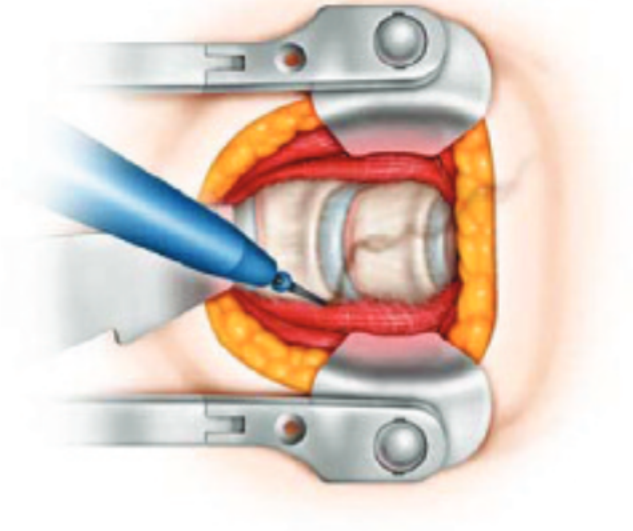
STEP 2 – SURGICAL APPROACH

A. Finger dissection



- Gently expose the prevertebral fascia using finger dissection.

B. Strip the longus colli



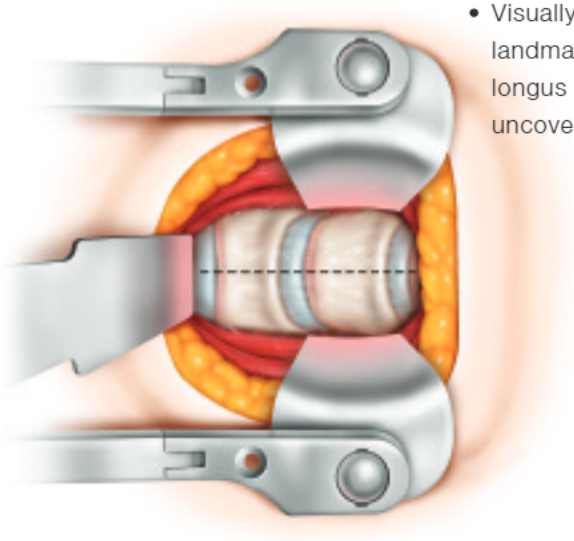
- Strip the longus colli a few millimeters off its medial attachment to expose the anterior surfaces of the vertebral bodies (subperiosteal exposure).

DISCOVER Artificial Cervical Disc **IMPLANTATION**

I. IDENTIFY MIDLINE

NOTE: Proper midline identification is critical to the success of the artificial disc implantation.

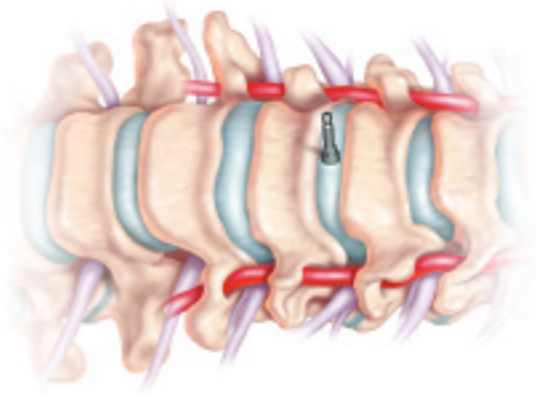
A. Identify midline



- Once the operative level has been exposed and confirmed, remove anterior osteophytes.
- Visually approximate the midline using anatomical landmarks such as the midpoint between the fibers of the longus colli muscle and/or the midpoint between the uncovertebral joints. These anatomical landmarks may vary.

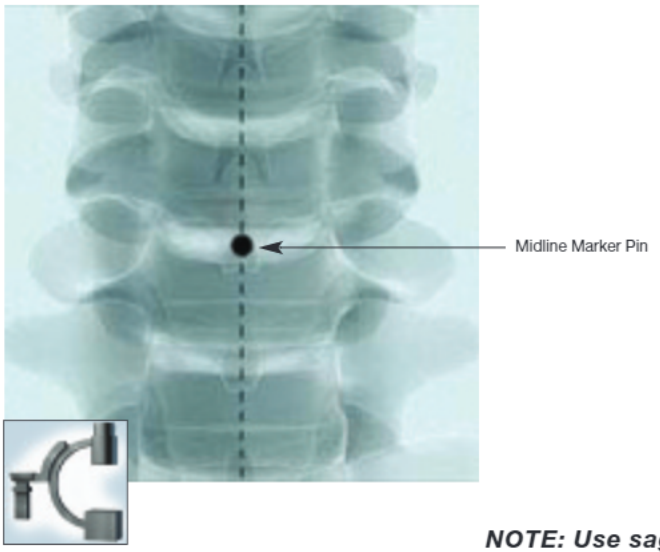
B. Mark midline

- Load the Midline Marker Pin into the Midline Marker Inserter.
- Insert the Midline Marker Pin into the disc in the frontal midline.
- Remove the Midline Marker Inserter leaving the Midline Marker Pin in the disc.



C. Confirm Midline Marker Pin is in midline position

- Confirm that the Midline Marker Pin is in the frontal midline of the vertebral bodies using A/P fluoroscopy.



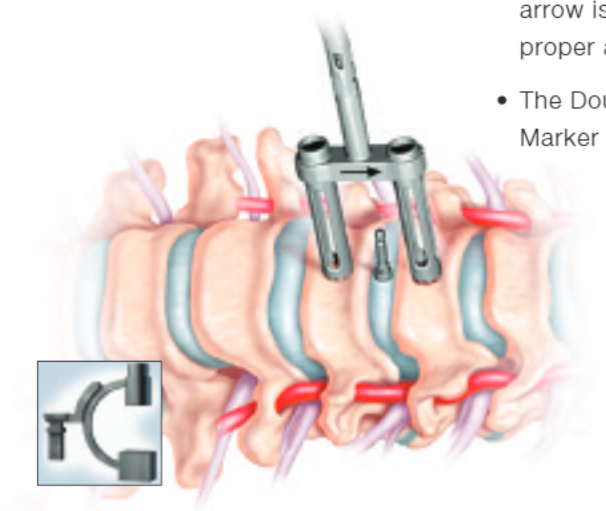
Fluoroscopy

NOTE: Use sagittal fluoroscopy as appropriate to confirm selection and placement of Vertebral Distraction Pins.

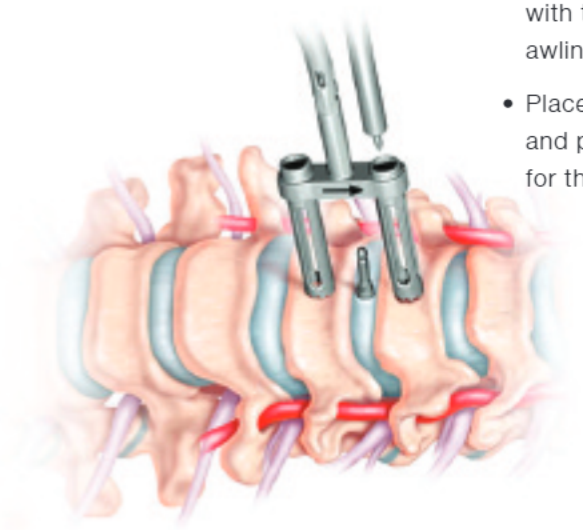
- Use the appropriately sized Double Barrel Guide, which will allow placement of the Vertebral Distraction Pins in the center (middle third) of each vertebral body, parallel to each other.
- The Double Barrel Guide handle can be rotated 180° to accommodate the operating surgeon's preference for a right-handed or left-handed approach.

D. Double Barrel Guide selection

- The Double Barrel Guide should be oriented so the indicator arrow is pointing in the cephalad direction to ensure the proper angle of the Vertebral Distraction Pin.
- The Double Barrel Guide should be aligned over the Midline Marker Pin.



E. Awl vertebral bodies



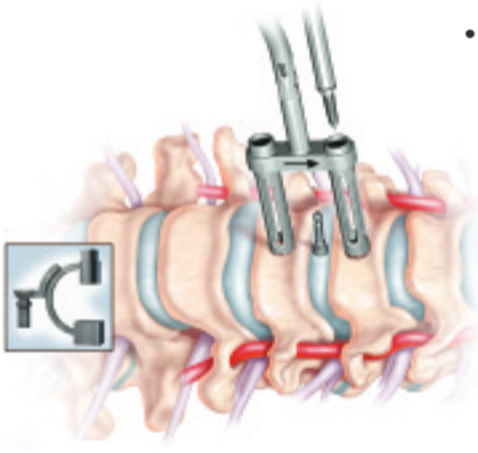
- Ensure that each barrel of the Double Barrel Guide is flush with the anterior surface of the vertebral bodies, prior to awling.
- Place the awl through the barrel of the Double Barrel Guide and penetrate the cortical bone of the vertebral body. Repeat for the second barrel.

F. Vertebral Distraction Pin selection

NOTE: The Vertebral Distraction Pins will be inserted in the frontal midline to serve as midline locators throughout the rest of the procedure.

- The thread length should be selected based on pre-operative or intraoperative imaging to ensure the pin inserts as far as possible into the vertebral body without penetrating the posterior cortex and entering the spinal canal.
- Vertebral Distraction Pins are provided in three lengths (12, 14, and 16mm) and two diameters (2.8 and 3.3mm).
- ***The 2.8mm diameter pins should be used first.*** In the event the pins become loose during the procedure, replace them with the 3.3mm diameter pins.

G. Vertebral Distraction Pin placement



- Load the first Vertebral Distraction Pin into the Distraction Pin Driver.
- Ensure that each barrel of the Double Barrel Guide is flush with the anterior surface of the vertebral bodies, prior to placing the Vertebral Distraction Pins.
- Insert the Vertebral Distraction Pin through the Double Barrel Guide and into the vertebral body.
- Use sagittal fluoroscopy during Vertebral Distraction Pin insertion to ensure the Vertebral Distraction Pin does not penetrate the posterior cortex and enter the spinal canal.

NOTE: The Stabilization Sleeve has been designed as an optional instrument, for use with the Double-Barrel Guide when placing the second Distraction Pin. By inserting the Sleeve over the first distraction pin as illustrated, the amount of toggle between the two instruments is reduced, and thereby minimizing the movement of the guide during the insertion of the second pin.

NOTE: If using the Stabilization Sleeve, place the Stabilization Sleeve over the first Vertebral Distraction Pin prior to inserting the second Vertebral Distractor Pin.

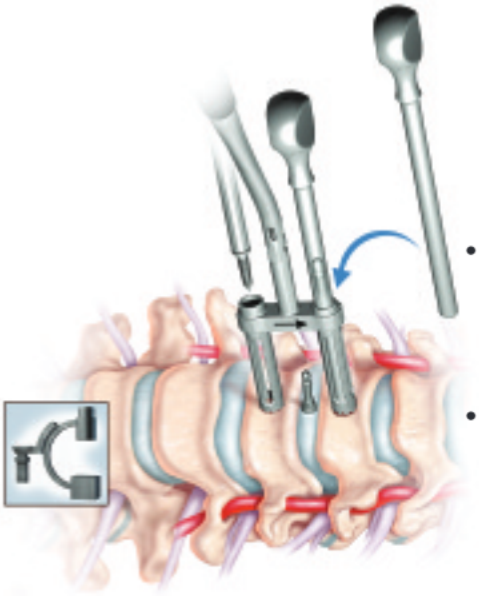


Image shown with Stabilization Sleeve

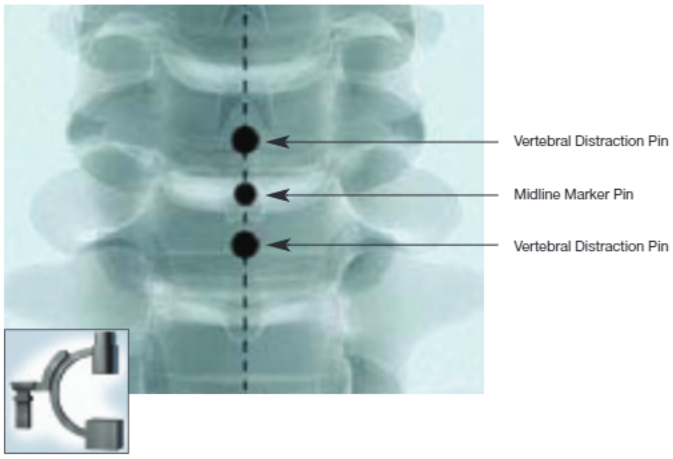
- Load the second Vertebral Distraction Pin into the Distraction Pin Driver and insert the Vertebral Distraction Pin through the other barrel of the Double Barrel Guide and into the vertebral body.
- Remove the Distraction Pin Driver, and the Double Barrel Guide.

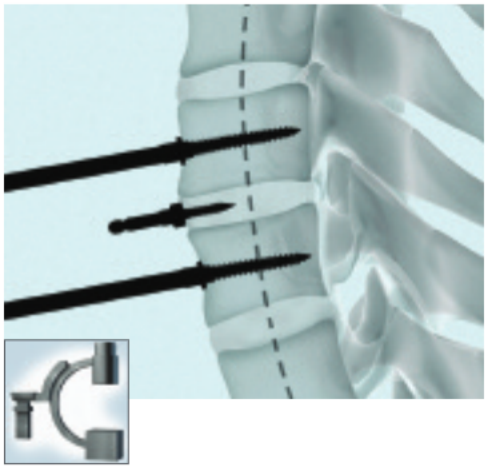
- Confirm that the Vertebral Distraction Pins have been placed in the frontal midline of the vertebral bodies using A/P fluoroscopy.

  NOTE: The Vertebral Distraction Pins are placed to promote parallel distraction of the disc space.

- Remove the Midline Marker Pin from the disc space using the Midline Marker Inserter.

H. Midline placement confirmation





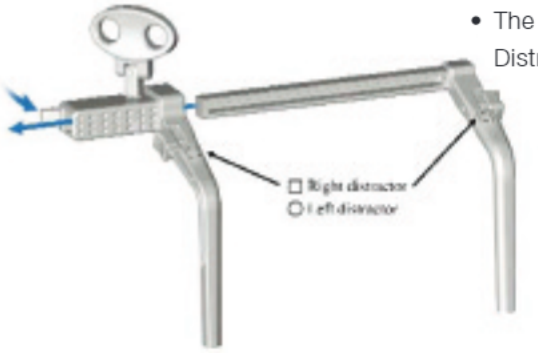
DISCOVER Artificial Cervical Disc **IMPLANTATION**

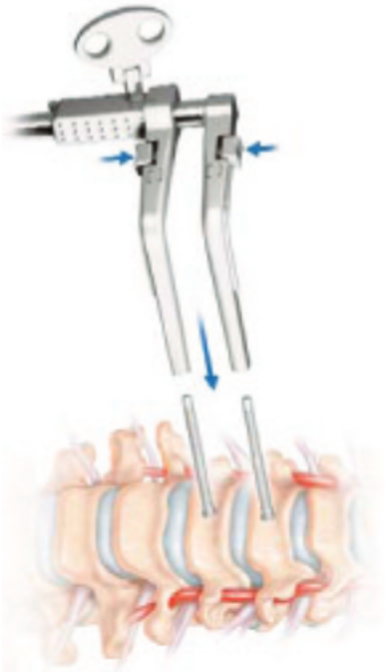
II. DECOMPRESS & PREPARE ENDPLATES

Vertebral Distractor Assembly

- ***At the end of this section of the procedure, the endplates must be flat before proceeding to the trialing step.***
- The Vertebral Distractors will come unassembled in two pieces. Care must be taken to assemble the two pieces for a left-sided approach versus the two pieces for a right-sided approach.
- Attach the Vertebral Distractor to the Vertebral Distraction Pins by depressing the locking arms on both side of the Vertebral Distractor.
- The Vertebral Distractor will interlock with the Vertebral Distraction Pins once the locking arms have been released.

A. Vertebral Distractor assembly





NOTE: Avoid over-distraction when opening the disc space.

NOTE: Do not compromise subchondral bone during preparation, especially in the center of the endplate.

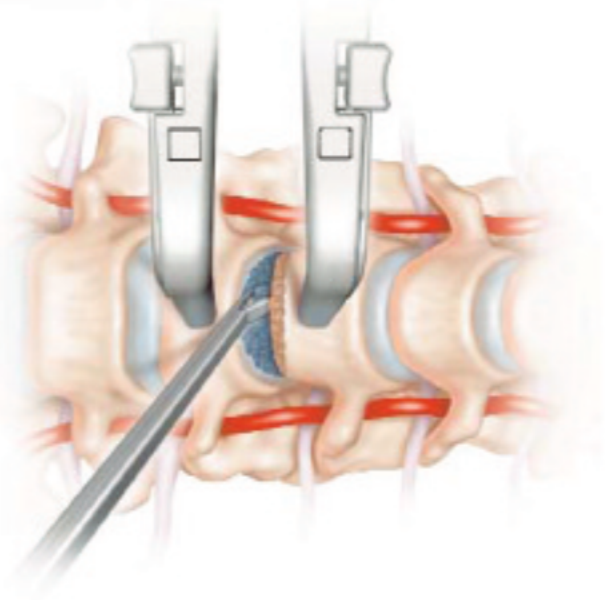
NOTE: As the intended benefit of arthroplasty is to maintain motion, it is important that a BILATERAL posterior decompression around the nerve root be thorough and complete.

- According to surgeon preference, use instruments such as pituitary rongeurs and curettes to perform a complete discectomy taking care to leave the lateral annulus intact.
- To relieve compression on the nerve root, if indicated, resect as much of the uncinate processes as necessary using standard burrs, drills, or a Kerrison rongeur.

CAUTION: Irrigate the area thoroughly following any burring to ensure all debris has been removed.

- If indicated, resect or release the posterior longitudinal ligament in order to allow for parallel distraction and/or to gain access to osteophytes causing spinal canal stenosis and nerve root compression. Remove posterior osteophytes and any herniated disc material.

B. Discectomy

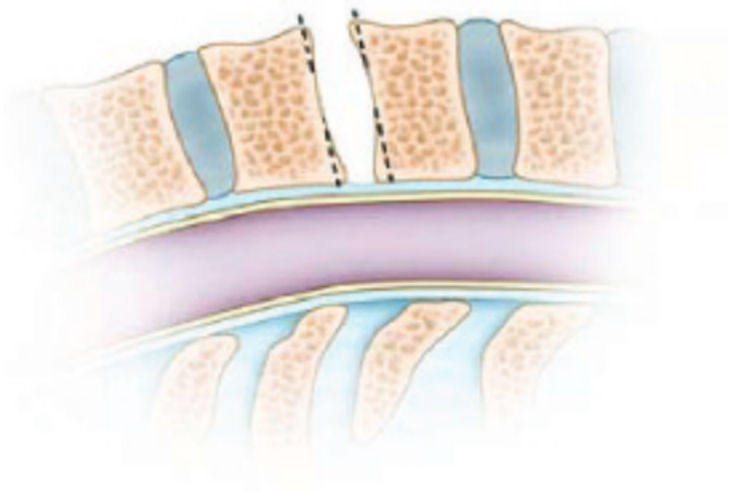


NOTE: To ensure proper fit and performance of the implant, it is important to prepare the vertebral endplates, by removing any anterior and posterior osteophytes, before proceeding to the trialing step.

- According to surgeon preference, a combination of burrs, curettes and rongeurs can be used, to ensure the endplates are flat. Do not compromise subchondral bone during endplate preparation, especially in the center of the vertebral endplate.
- Particular attention should be paid to the supra-adjacent endplate to ensure the concavities are flattened. This will optimize contact between the vertebral and implant endplates.
- If necessary, prepare the uncinate processes depending on patient anatomy. (A partial symmetrical uncinate removal may be required.)
- Prepare the disc space/vertebral endplates to most appropriately accommodate the seven-degree angle of the prosthesis.

CAUTION: Irrigate the area thoroughly following any burring to ensure all debris has been removed.

C. Endplate preparation

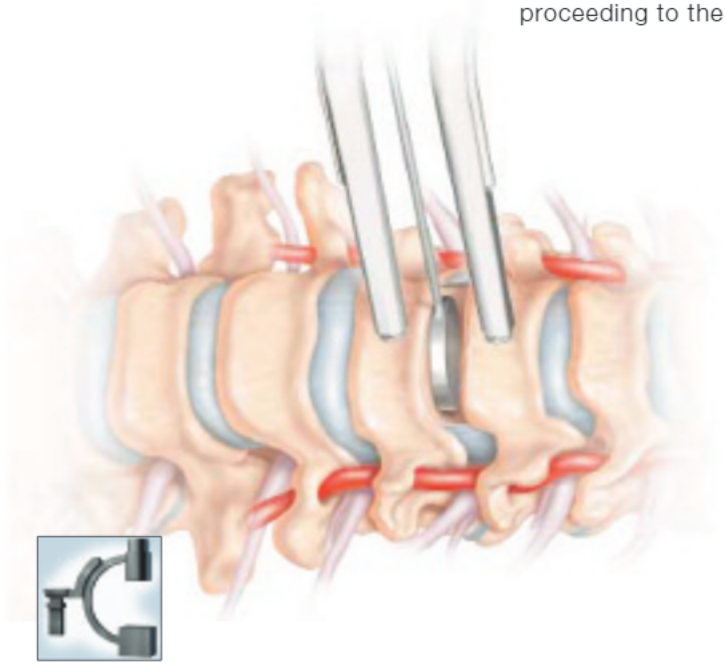


- Select the Footprint Sizing Gauge that maximizes vertebral endplate coverage while remaining within the disc space.

  NOTE: Rasps are provided for additional endplate preparation if necessary. If rasping is required, choose the Rasp that corresponds to the previously determined footprint size.

- Confirm that the vertebral endplates are flat before proceeding to the Trialing step.

D. Footprint sizing and rasping

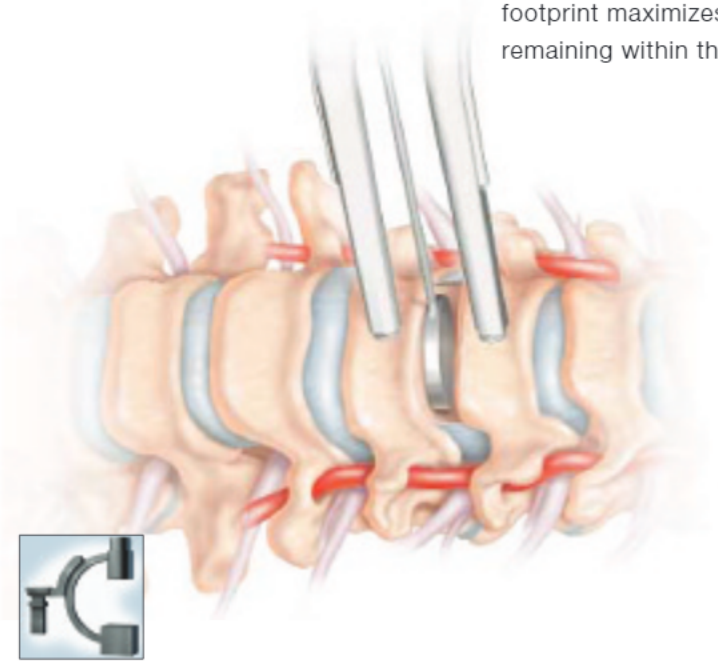


DISCOVER Artificial Cervical Disc IMPLANTATION

III. **TRIALING**

A. Footprint Confirmation

- Use Footprint Sizing Gauges to confirm that the selected footprint maximizes vertebral endplate coverage while remaining within the disc space.

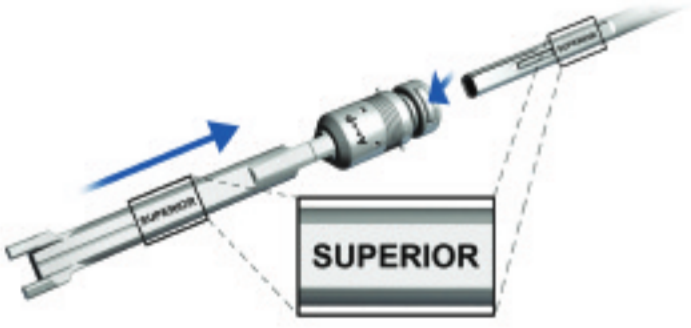


NOTE: The A/P Stop has been designed as an optional instrument.

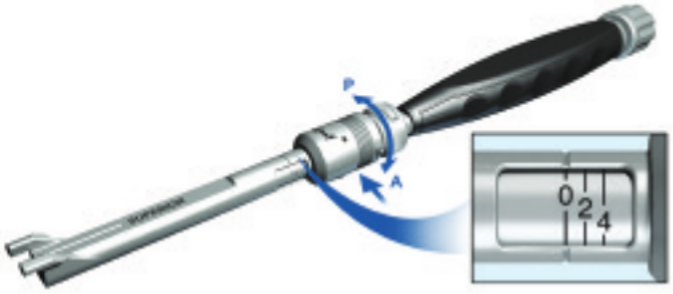
- The A/P Stop is used in conjunction with the Inline Inserter and Grabber Tip to provide incremental translational adjustment during insertion of the Trial/Implant.
- Once the depth of the trial is confirmed during the trialing step, the value on the A/P Stop can be noted through the window, as illustrated, and locked in place. This will provide a consistent reference point when inserting the actual prosthesis during the final implantation step.

B. Attach A/P Stop to the Disc Insertion Tool

- Line up the push-button located at the end of the A/P Stop with the engraved A⟷P arrow and the "SUPERIOR" etching on the opposite end.
- Prior to attaching the A/P Stop to the Disc Insertion Tool, align the "SUPERIOR" etching on each piece as shown in Step 1.
- To assemble the A/P Stop to the Disc Insertion Tool, depress the push-button on the A/P Stop and slide the A/P Stop fully onto the Disc Insertion Tool as shown in Step 1 and 2. Release the push-button.
- Ensure the A/P Stop is fully locked into place by gently tugging on the A/P Stop.
- Set the A/P Stop to "0" by pushing the lever and rotating the outer barrel as shown in Step 2.



Step 1



Step 2

C. Disc Trial

NOTE: Grabber Tips are sized to match the Disc Trial heights.

- The Disc Trial height can be estimated using pre-operative or intraoperative imaging techniques.
- The Disc Trial corresponds to the footprint and angle of the implant. The height of the Disc Trial represents the implant minus the fixation teeth (1 mm each on the superior and inferior endplates).
- Select the Disc Trial with a height appropriate to the disc space for the operative level.
- ***Select the Grabber Tip (etched with height size) that corresponds to the selected Disc Trial height.***
- Assemble the Grabber Tip to the Disc Insertion Tool as shown in Step 3. Place the Grabber Tip into the end of the Disc Insertion Tool and turn the knob on the Disc Insertion Tool clockwise to securely engage the threads in the Grabber Tip.
- Load the Disc Trial onto the Grabber Tip by turning the knob on the Disc Insertion Tool clockwise until secure.

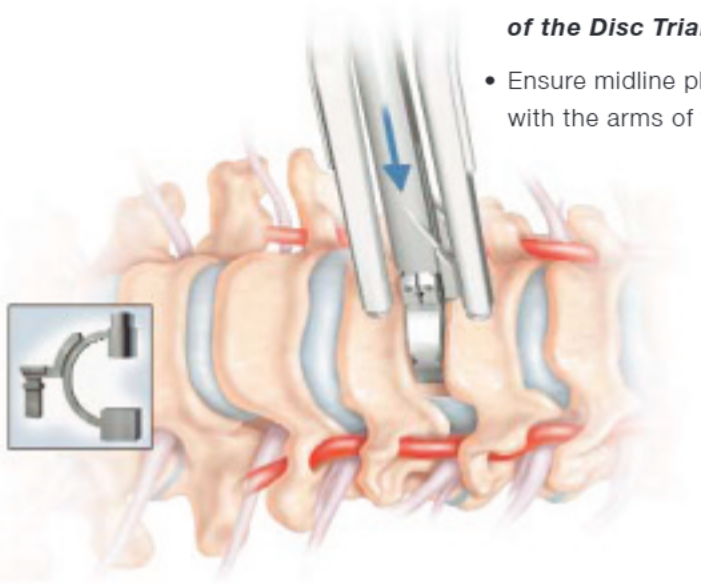
Step 3

NOTE: Use sagittal and A/P fluoroscopy to determine the size and continually monitor insertion and progression of the Disc Trial.

- Insert the Disc Trial into the disc space under fluoroscopy. Without overdistracting, apply additional incremental distraction as necessary.

NOTE: A midline groove is engraved on the Disc Insertion Tool to assist with frontal midline placement of the Disc Trial.

- Ensure midline placement by inserting the Disc Trial in line with the arms of the Vertebral Distractor.



If using the A/P Stop:

NOTE: The A/P Stop should contact the anterior surface of the superior vertebral body. It is important to maintain this orientation throughout the trialing and implantation steps.

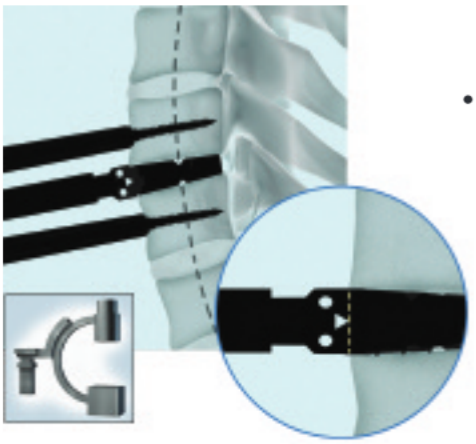
NOTE: A midline groove is engraved on the A/P Stop to assist with frontal midline placement of the Disc Trial.

- During disc height trialing, the A/P Stop can be adjusted. Depress the lever to unlock the barrel. While rotating the barrel, release the lever, and continue rotating until the barrel locks again. Adjust as necessary until the Disc Trial is in the desired position.

  "P" = Clockwise, allows for posterior advancement.

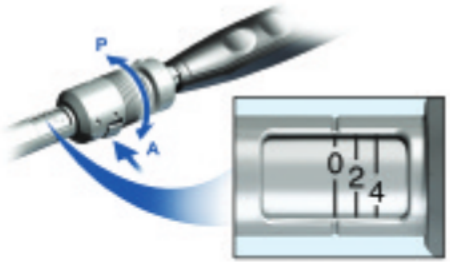
  "A" = Counterclockwise, allows for anterior withdrawal.

D. Sagittal fluoroscopy image



- ***Release any remaining distraction on the Vertebral Distractor to ensure accurate assessment of disc space height while assessing endplate contact (apposition).***
- Use sagittal fluoroscopy to confirm:
    1. The selected Disc Trial provides the desired disc space height.
    2. The grooved center of the Disc Trial is at or slightly posterior to the sagittal midline of the vertebral bodies.
    3. There is good apposition between the vertebral endplates and the surface of the Disc Trial.

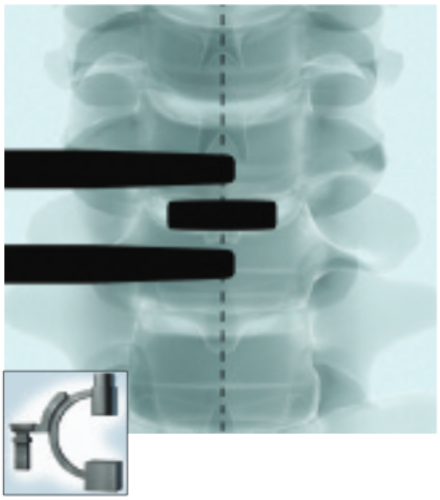
NOTE: Under fluoroscopy the point of the triangle indicates the anterior surface of the Disc Trial as shown in the close-up view. Round holes in the Grabber Tips are used to align the Disc Trial in the sagittal plane.



If using the A/P Stop:

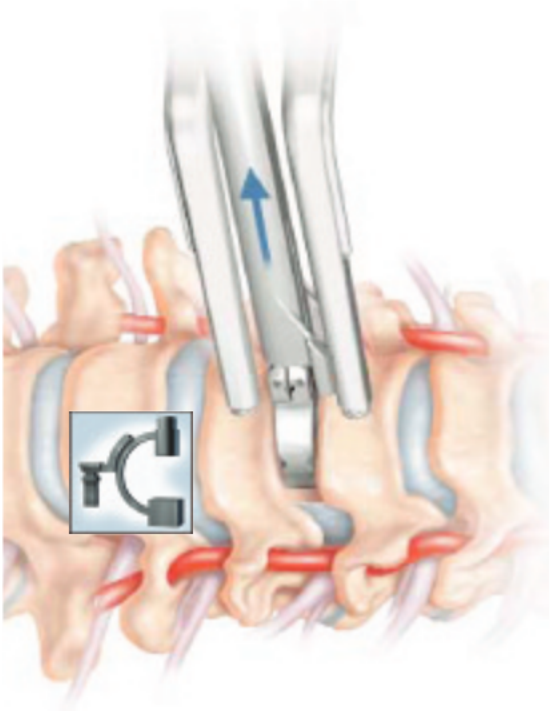
- Once sagittal positioning is achieved, make note of the final position on the A/P Stop during trialing by reading the numerical value.
- By maintaining the position of the A/P Stop attained during trialing, the implant can be inserted to the same relative depth.

E. A/P fluoroscopy



- Use A/P fluoroscopy to confirm:
    1. The Disc Trial is positioned in the frontal midline of the vertebral bodies.
    2. There is good apposition between the vertebral bodies and the surface of the Disc Trial.

F. Intraoperative Removal



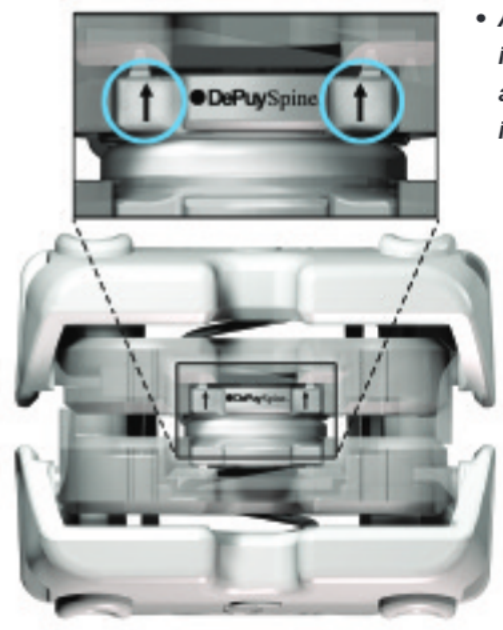
- The Disc Trial and Grabber Tip should be removed and another Disc Trial and matching Grabber Tip should be selected if:
    1. The resulting disc space height is not appropriate relative to adjacent levels.
    2. The center of the Disc Trial cannot be placed at the sagittal midline (or slightly posterior) of the vertebral bodies.
    3. The Disc Trial does not provide adequate endplate coverage.
- The Disc Trial should be removed and further endplate preparation performed if:
    1. There is evidence of radiolucency between the surface of the vertebral bodies and the surface of the Disc Trial.
    2. The Disc Trial cannot be placed in the frontal midline due to asymmetrical or incomplete disc space preparation.
- Return to Section II, Step C (Flat Endplate Preparation)

DISCOVER Artificial Cervical Disc **IMPLANTATION**

IV. IMPLANT INSERTION

A. Load implant

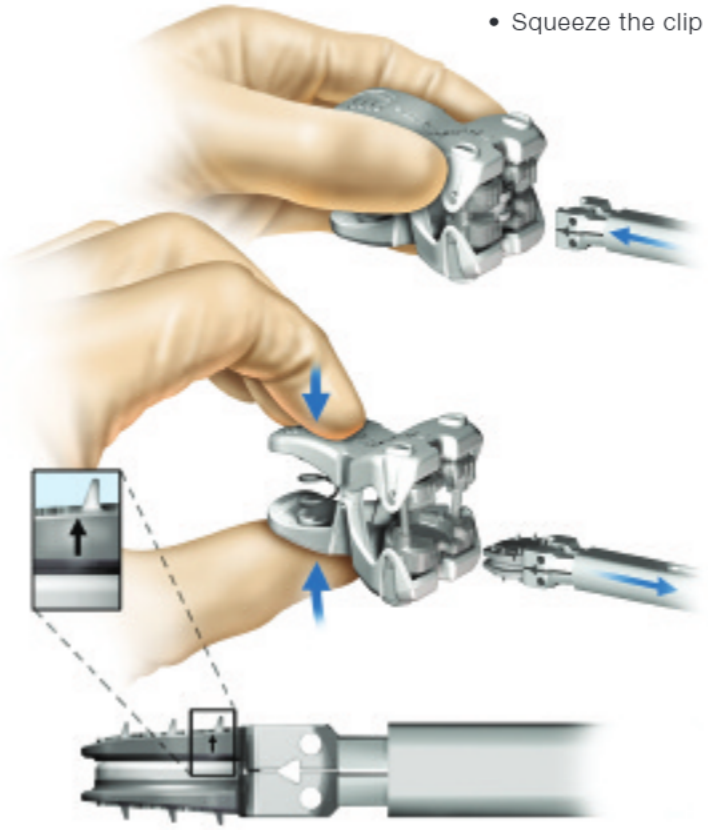
- The DISCOVER Artificial Cervical Disc is supplied in a holder clip within a double sterile pouch.
- When removing the clip from the pouch, take care to avoid squeezing the clip and prematurely disengaging the implant.



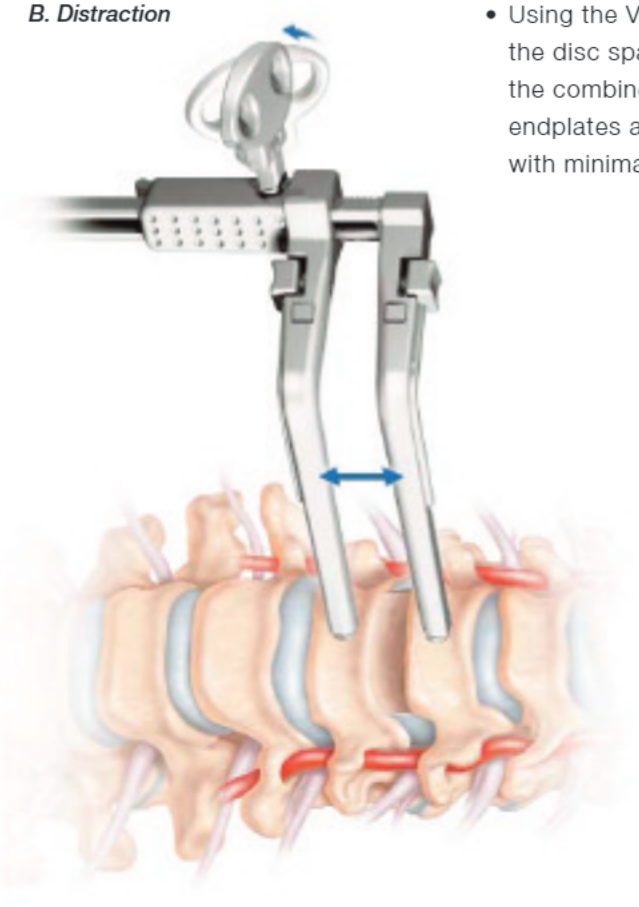
- ***Arrows are etched on the superior endplate of the implant. Care must be taken to ensure that these arrows are pointed in the cephalad direction during insertion of the implant into the disc space.***

- ***Prior to loading the implant onto the Disc Insertion Tool, confirm that the Grabber Tip height corresponds to the selected implant height.***

- While loading the implant, ensure the implant and A/P Stop are oriented in the direction shown below.
- Load the implant onto the Grabber Tip by turning the knob on the Disc Insertion Tool clockwise until secure. Ensure that the implant is securely held to the Grabber Tip by gently rotating the clip. If not secure, reload the implant onto the Grabber Tip.
- Squeeze the clip to release the implant.

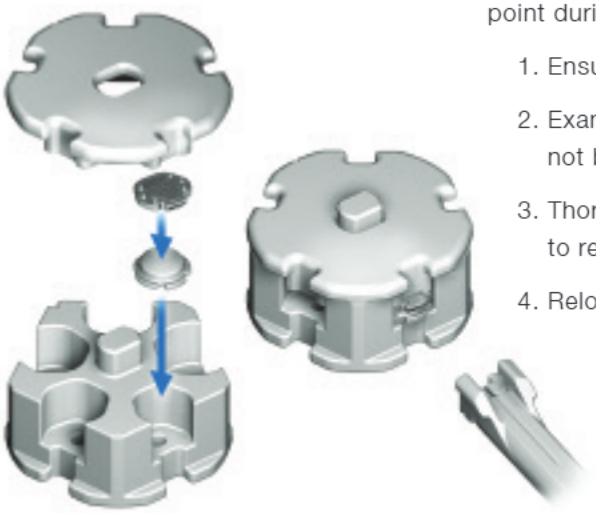


B. Distraction



- Using the Vertebral Distractor, increase the distraction across the disc space by approximately 2mm. This corresponds with the combined height of the teeth on the superior and inferior endplates and will ensure that the implant can be inserted with minimal impaction force.

C. Implant reloading (IF NEEDED)



- If the implant disengages from the clip or grabber tip at any point during the procedure:
  1. Ensure implant sterility has not been compromised.
  2. Examine the articulating surfaces to ensure they have not been damaged.
  3. Thoroughly rinse the implant with a sterile saline solution to remove any debris.
  4. Reload the implant using the Disc-Loading Block.

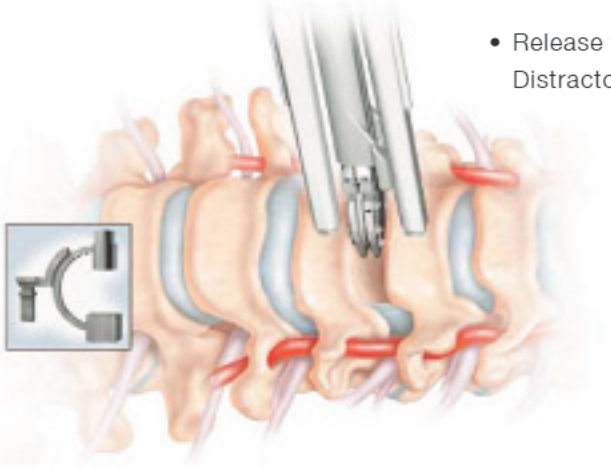
NOTE: Before insertion, confirm the correct device orientation as indicated by the arrows pointing in the cephalad direction.

- The implant should be inserted using fluoroscopy to monitor the depth in the sagittal plane.
- Insert the DISCOVER Artificial Cervical Disc in the frontal midline.

NOTE: During insertion of the implant, maintain a neutral orientation of the insertion shaft to the vertebral disc space. (Avoid biasing the instrument in the Cephalad or Caudal direction.)

- Once the DISCOVER Artificial Cervical Disc has been implanted to the desired depth, disengage the Disc Insertion Tool by turning the knob counter-clockwise.
- Release the distraction applied across the Vertebral Distractor.

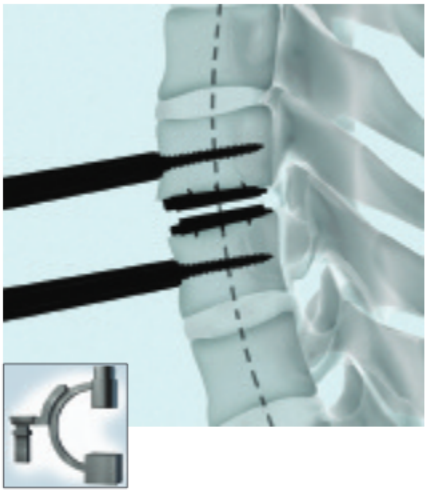
D. Implant insertion



If using the A/P Stop:

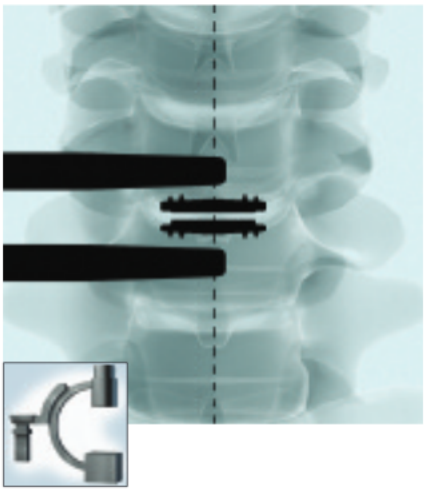
- The A/P Stop should contact the anterior surface of the superior vertebral body as shown in the image. It is important to maintain this orientation throughout the steps for implant insertion.
- Confirm that the numerical value of the A/P Stop is the same as was noted during the trialing step.
- Insert the DISCOVER Artificial Cervical Disc in the frontal midline. The arms of the Vertebral Distractor can be used as a guide with the midline groove engraved on the A/P Stop.

E. Sagittal position confirmation



- Use a sagittal fluoroscopic image to confirm:
  1. The middle tooth of the implant is slightly behind the sagittal midline of the vertebral bodies.
  2. There is good apposition (i.e., minimal radiolucency) between the vertebral endplates and the implant.
  3. The fixation teeth are properly engaged in the vertebral bodies.

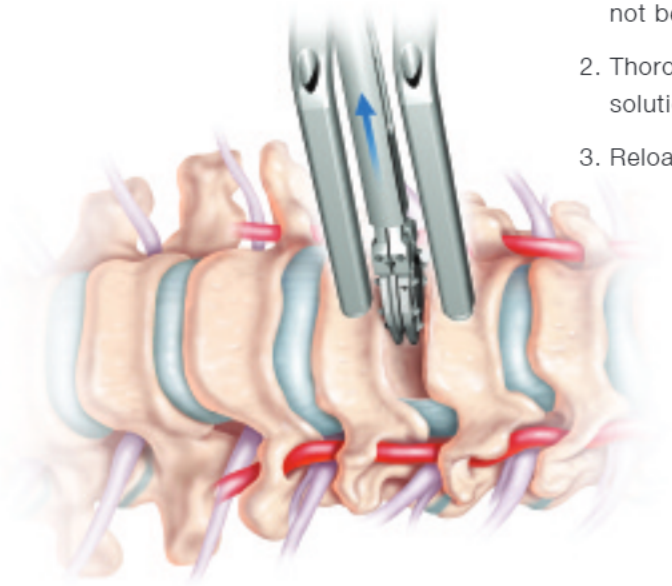
F. A/P plane position confirmation



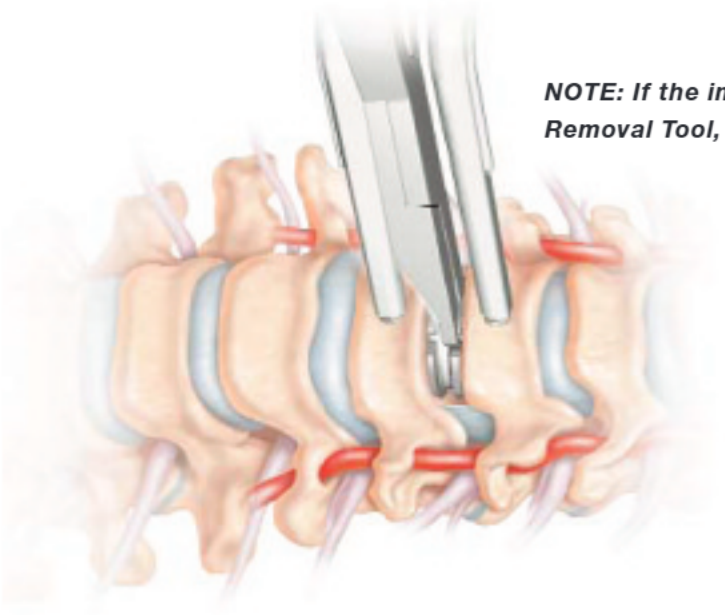
- Use an A/P fluoroscopic image to confirm:
  1. Correct positioning of the implant in the frontal midline.
  2. There is good apposition (i.e., minimal radiolucency) between the vertebral endplates and the implant endplates.
- The Vertebral Distractor can be used to apply compression to the implant to better seat the fixation teeth.

- The DISCOVER Artificial Cervical Disc should be removed if:
    1. It is malpositioned in either the frontal or sagittal planes.
    2. Further endplate preparation is required to allow good apposition (i.e., minimal radiolucency) between the vertebral endplates and implant endplates.
    3. Further endplate preparation is required to allow better engagement of the teeth.
- In the event it is necessary to remove the DISCOVER Artificial Cervical Disc, use the Grabber Tip of the Disc Insertion Tool to engage the implant and remove the assembly, then:
    1. Examine the articulating surfaces to ensure they have not been damaged.
    2. Thoroughly rinse the implant with a sterile saline solution to remove any debris.
    3. Reload the implant using the Disc-Loading Block.

G. Intraoperative removal



H. Implant revision



- If the implant cannot be properly engaged with the Disc Insertion Tool, the Disc Removal Tool can be used to explant the disc.

NOTE: If the implant has been removed using the Disc Removal Tool, it should not be reimplanted.

Notes

Notes

DISCOVER™
ARTIFICIAL CERVICAL DISC

U.S. Investigational Device

INDICATIONS

The Discover Artificial Cervical Disc is indicated for the treatment of symptomatic cervical degenerative disc disease at one level between C3 and C7 presenting with:

- Neck or arm (radicular) pain;
- A functional/neurological deficit with at least one of the following conditions confirmed by imaging (CT, MRI or Xrays):
  - Herniated nucleus pulposus;
  - Spondylosis (defined by the presence of osteophytes); and/or
  - Loss of disc height.

CAUTION: Investigational Device. Limited by Federal (or United States) law to Investigational use.

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