

### Indications

The Discover™ Artificial Cervical Disc is indicated for the treatment of symptomatic cervical degenerative disc disease at one or two levels between C3 and C7 in patients 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 X-rays):
  - Herniated nucleus pulposus;
  - Spondylosis (defined by the presence of osteophytes); and/or
  - Loss of disc height.

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Discover™ Surgical Technique

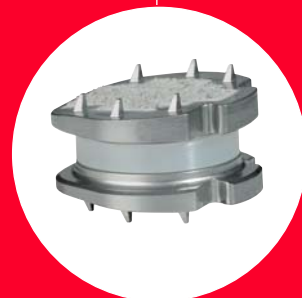


 **DePuySpine**™  
a *Johnson & Johnson* company



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## Indications for Use

The Discover™ Artificial Cervical Disc is indicated for the treatment of symptomatic cervical degenerative disc disease at one or two adjacent levels between C3 and C7 in patients 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 X-rays):
  - Herniated nucleus pulposus;
  - Spondylosis (defined by the presence of osteophytes); and/or
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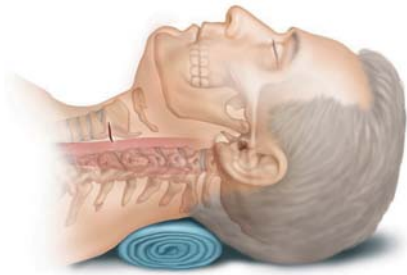
## Pre-Operative Planning

It is a pre-requisite that, due to the variability of each patient, the surgeon has available the range of necessary images in order to be equipped to plan the operation appropriately

## Patient Positioning

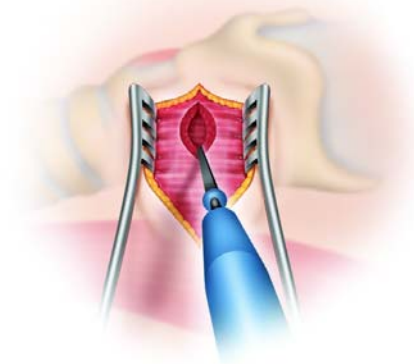
The patient should be placed on a radiolucent operating table that will allow for circumferential C-arm movement.

**Step 1: Patient Positioning**



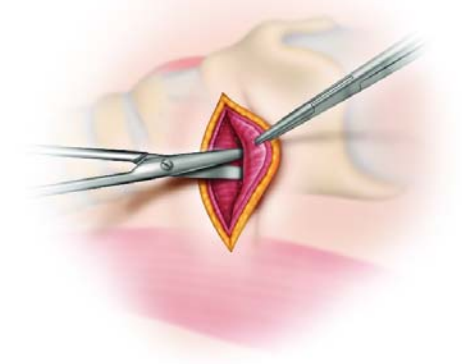
**1. Position Patient**

- Position the patient supine and drape according to standard operating room protocols.
- 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 left or right.
- It is recommended that the mid-cervical spine 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 stabilisation.



**2. Skin Incision**

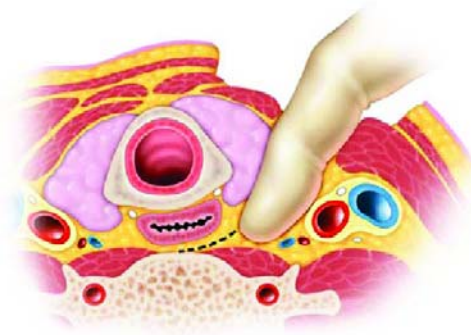
- Once radiographic confirmation of the anatomy is complete, create a skin incision over the appropriate disc space.



**3. Incise the Platysma**

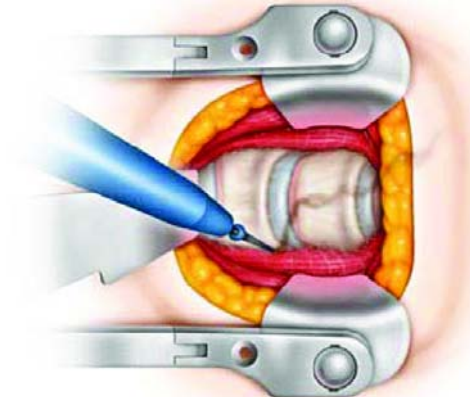
- Undermine and then incise the platysma.

## Step 2: Surgical Approach



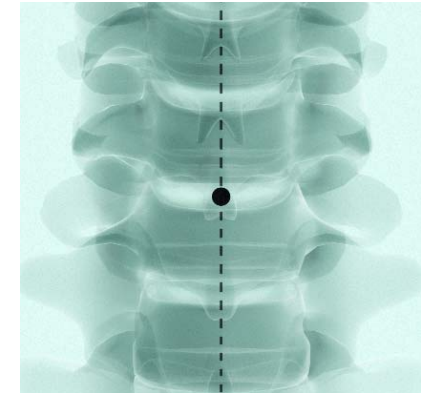
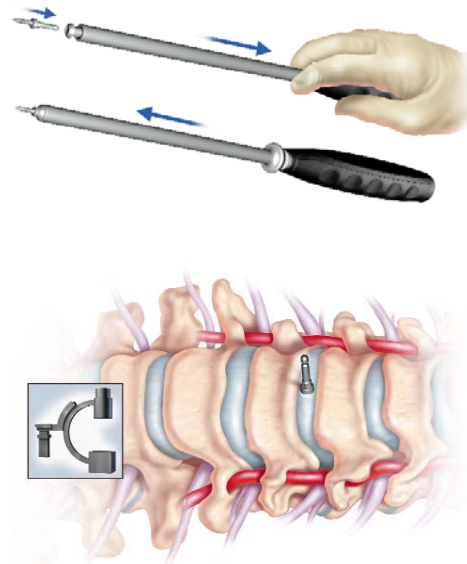
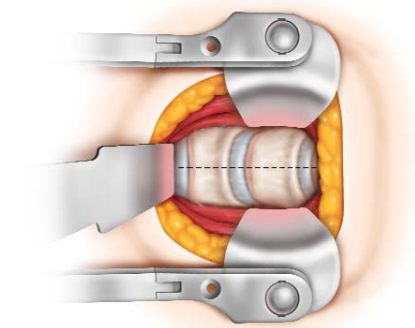
### 1. Finger Dissection

- Gently expose the prevertebral fascia using finger dissection.



### 2. Strip the Longus Coli

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



### 1. Identify Midline

- **Accurate midline identification is a key part of the implantation procedure.** The Discover™ Artificial Cervical Disc should be implanted in the frontal midline of the spine.
- Once the operative level has been exposed and confirmed by sagittal fluoroscopy remove anterior osteophytes.
- Approximate the midline using anatomical landmarks such as the midpoint between the fibres of the longus coli muscle and/or the midpoint between the uncovertebral joints.

### 2. Mark Midline

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

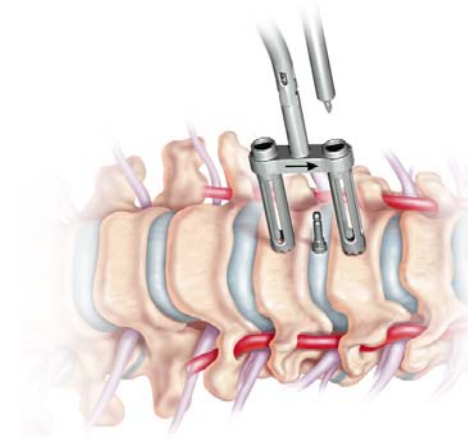
### 3. Confirm Marker Pin is in Midline Position

- Take an A/P fluoroscopic image to confirm that the Midline Marker Pin is in the frontal midline of the vertebral bodies.



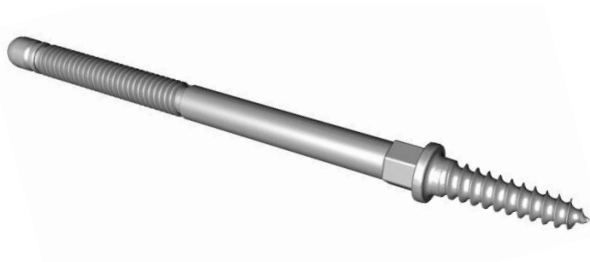
#### 4. Double Barrel Guide Selection

- Various Double Barrel Guides are provided to ensure Vertebral Distraction Pins are positioned parallel with each other.
- Use the Double Barrel Guide, which allows placement of the Vertebral Distraction Pins in the centre (middle third) of the two vertebral bodies.
- The Double Barrel Guide head can be rotated 180° to accommodate the operating surgeon's preference for a right-handed or left-handed approach.
- The Double Barrel Guide should be oriented so that the indicator arrow is pointing in the cephalad direction to ensure proper angle of distractor pin placement.
- The Double Barrel Guide should be aligned over the Midline Marker Pin in the previously determined midline.



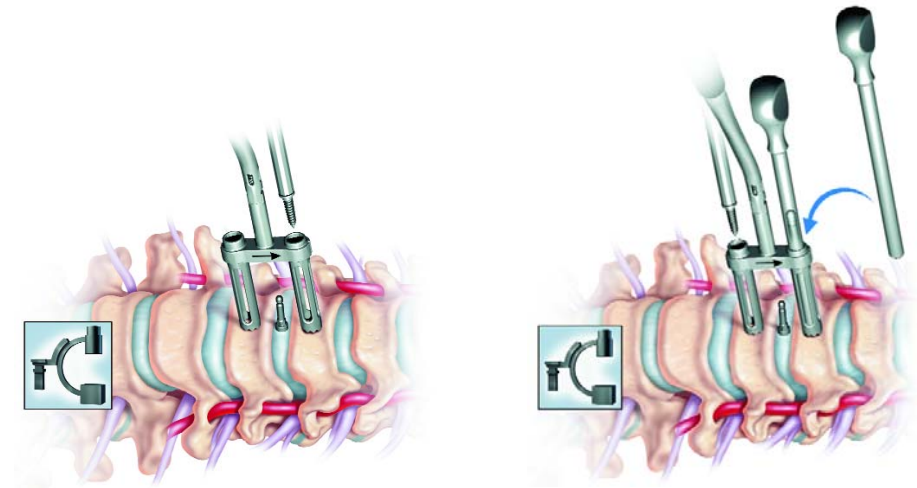
#### 5. Awl Vertebral Bodies

- Ensure that each barrel of the Double Barrel Drill Guide is flush with the anterior surface of the vertebral bodies prior to use of the awl.
- Use the Awl to penetrate the cortical bone of the vertebral bodies through the barrels of the Double Barrel Guide.



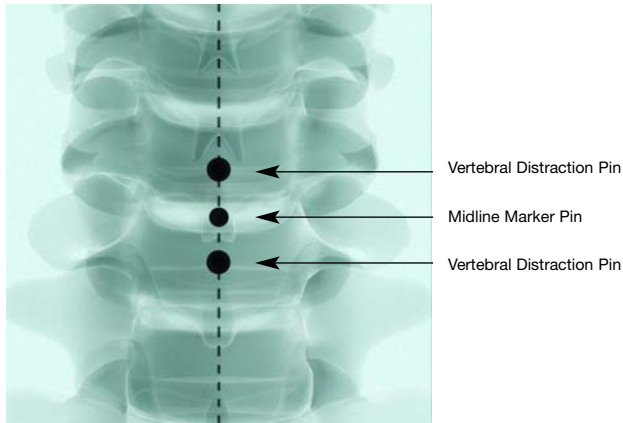
#### 6. Vertebral Distraction Pin Selection

- **The Vertebral Distraction Pins will be inserted in the frontal midline and will serve as midline locators throughout the rest of the procedure.**
- Vertebral Distraction Pins are provided in various lengths and diameters.
- **The 2.8mm diameter pins should be used first.**  
Should the pins become loose during the procedure, replace them with the 3.3mm diameter pins.
- The thread length should be selected so that the pin inserts as far as possible into the vertebral body without penetrating the posterior cortex and violating the spinal canal.



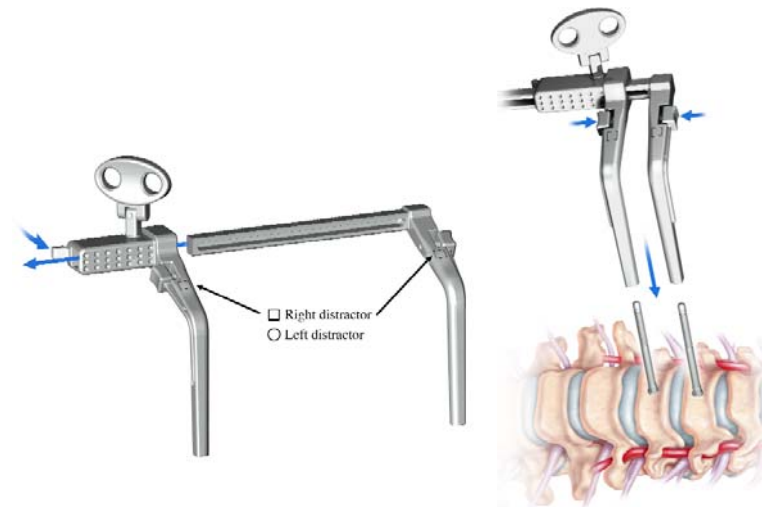
#### 7. Pin Placement

- Load the first Vertebral Distraction Pin into the Distraction Pin Driver and insert the pin into the vertebral body through the barrel of the Double Barrel Guide.
- Use sagittal fluoroscopy during pin insertion to ensure the pin does not penetrate into the spinal canal.
- Remove the Distraction Pin Driver and insert the Double Barrel Guide Stabilisation Sleeve over the Distraction Pin into the Double Barrel Guide.
- Load the second Vertebral Distraction Pin into the Distraction Pin Driver and insert the pin into the vertebral body through the barrel of the Double Barrel Guide.
- Use sagittal fluoroscopy during pin insertion to ensure the pin does not extend into the spinal canal.
- Remove the Stabilisation Sleeve and the Double Barrel Guide.



## 8. Midline Placement Confirmation

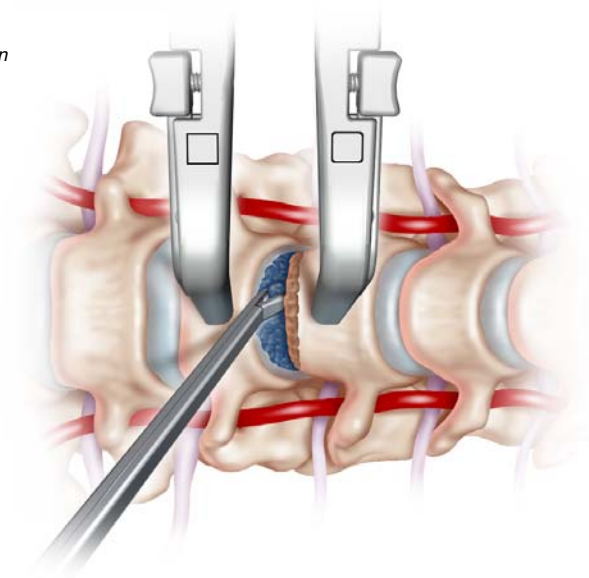
- Take an A/P fluoroscopic image to confirm that the Vertebral Distraction Pins have been placed in the frontal midline of the vertebral bodies.
- Remove the Midline Marker Pin from the disc space.



## 1. 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 either side of the Vertebral Distractor.
- The Vertebral Distractor will interlock with the Vertebral Distraction Pins once the locking arms have been released.

**Note:** Avoid over-distraction when opening the disc space



## 2. Discectomy

**Note:** Do not compromise subchondral bone during preparation, especially in the centre of the endplate.

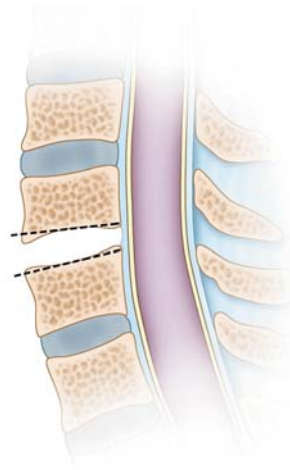
- According to surgeon preference, use instruments such as pituitary rongeurs and curettes to perform a complete discectomy.
- As the disc material is removed, additional incremental distraction and exposure of the disc space may be possible.
- If indicated, resect the uncinata processes using standard burs, drills, or a Kerrison rongeur to relieve compression on the nerve root.
- Do not use metallic irrigation and/or suction tubes whilst using a burr. This will eliminate the risk of generating metallic debris within the intradiscal space, should the burr contact the irrigation or suction tube.

- Irrigate the area thoroughly following any use of a burr.
- 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.

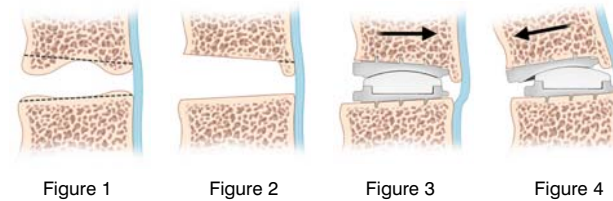
**Note:** It is critically important that the decompression around the nerve root be thorough and complete.

- Once adequate discectomy and decompression of the neural elements is achieved, release the distraction.

**Note:** Prepare the disc space/vertebral endplates to most appropriately accommodate the seven-degree angle of the prosthesis.



**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..



**Note:** During preparation of the endplate to best accommodate the 7° angle of the implant (Fig. 1) and to prevent against anterior displacement post-operatively (Fig. 4), it is important to ensure the removal of any superior posterior overhanging endplate material present (Fig. 2). If any bone of this nature is not removed, the potential exists to inadvertently push posteriorly the superior vertebral body during insertion of the device (Fig. 3).

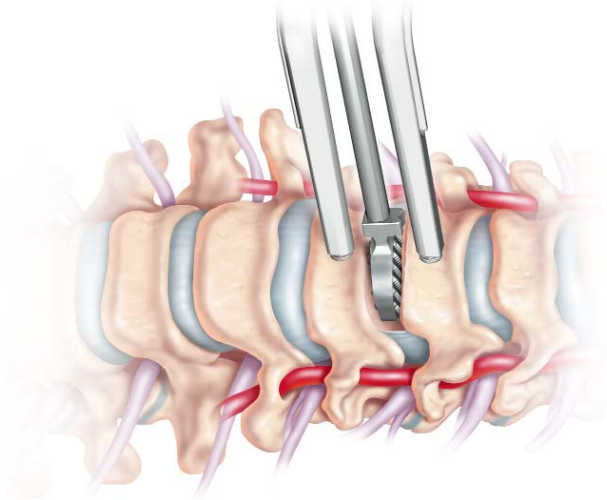
Failure to pay attention to this detail may result in sub-optimal implant placement and a post-operative kyphotic appearance.

## 1. Endplate Preparation

- According to surgeon preference, a combination of burrs, curettes, rongeurs, and rasps can be used, to ensure the endplates are flat. Do not compromise subchondral bone during endplate preparation, especially in the centre of the vertebral endplate.
- Particular attention should be paid to the supra-adjacent endplate to ensure the concavities are flattened. This will optimise contact between the vertebral and prosthetic endplates.

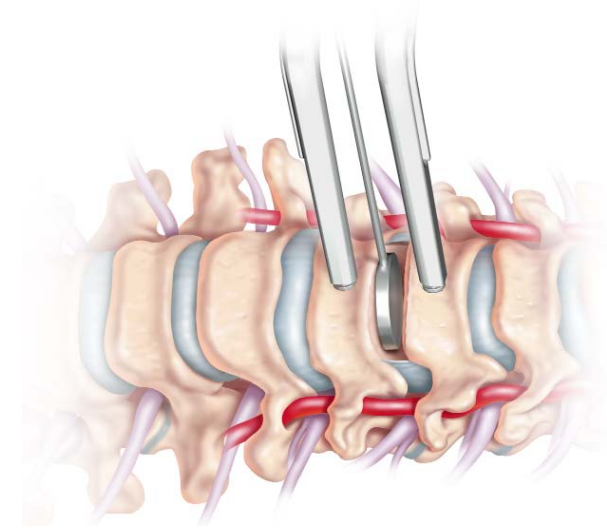
- Prepare the disc space / vertebral endplates to most appropriately accommodate the seven-degree angle of the prosthesis.
- If necessary, prepare the uncinate processes depending on patient anatomy. (A partial symmetrical uncinate removal may be required)

**Note:** Irrigate area thoroughly following any burring.



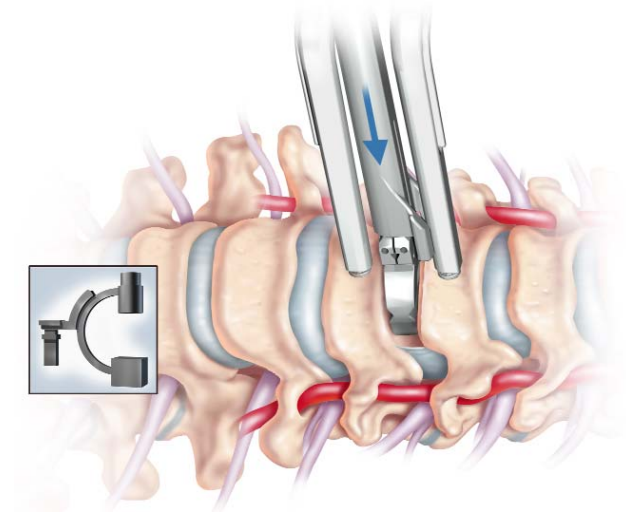
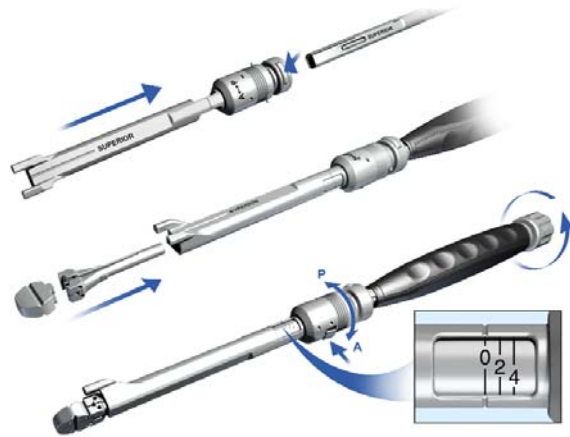
**2. Rasp Endplates**

- Final endplate preparation can be achieved using the rasps provided.
- The rasps are sized to match the Discover™ Artificial Cervical Disc footprints for accurate endplate preparation.



**1. Footprint Sizing**

- Use the Footprint Sizing Gauges to determine which footprint will most adequately cover the prepared endplates.
- Select the footprint that maximises vertebral endplate coverage while remaining entirely within the disc space.



## 2. Disc Trial

- Select the Disc Trial that corresponds to the previously selected footprint and with a height that is estimated to recreate the desired disc height at the operative level. This height can be estimated using pre-operative, intra-operative imaging techniques, and/or comparison with adjacent levels.
- The A/P Stop is used in conjunction with the Disc Inserter and Grabber Tip to provide incremental translational adjustment during insertion of the Trial/Implant. Load the A/P Stop onto the Disc Inserter and set the A/P Stop at 0. To attach the A/P Stop to the Disc Inserter, line up the push-button at the end of the A/P Stop with the A/P arrow graphic and align the two flat surfaces marked superior.

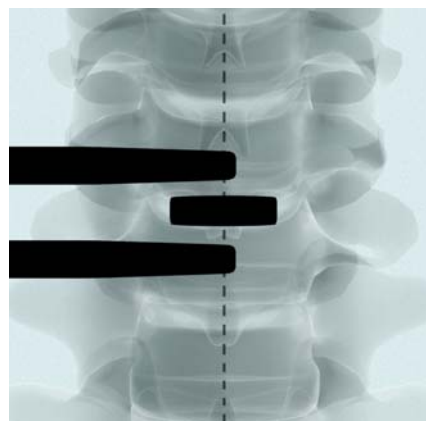
Depress the push-button and slide the A/P Stop fully onto the Disc Inserter as shown. Release the push-button and ensure the A/P Stop is locked into place.

- Load the Grabber Tip onto the Disc Inserter.
- Load the Disc Trial onto the Grabber Tip
- Insert the Disc Trial using the Disc Inserter
- Ensure midline placement by inserting the Disc Trial in line with the Vertebral Distraction Pins.
- 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.



### 3. Sagittal Fluoroscopy Image

- Continually monitor insertion and progression of the Disc Trial under fluoroscopy.
- Monitor the position of the A/P Stop visually and/or with the use of fluoroscopy. Adjust the A/P Stop incrementally as needed to optimise positioning of the Disc Trial. Perform this step with fluoroscopy.
- The device should be positioned as far posterior as possible ensuring that both the superior and inferior endplates of the device align.
- Release any remaining distraction on the Vertebral Distractor and/or traction device that may be in use to ensure accurate assessment of disc space height.
- Use sagittal fluoroscopy to confirm:
  1. The selected Trial provides the desired disc space height,



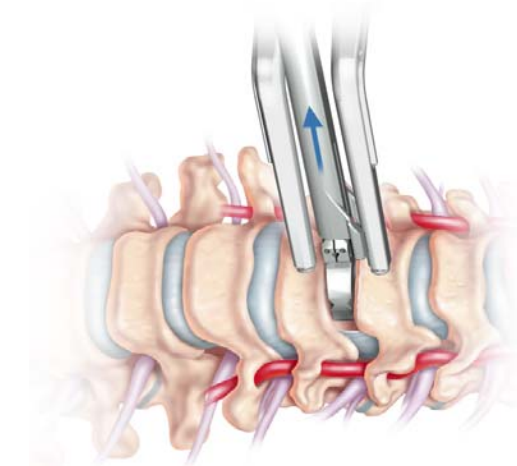
**Note:** Make note of the final position of the A/P Stop during trialing so that the implant can be inserted into the same relative position

2. The grooved centre of the Trial is at the sagittal midline of the vertebral bodies,
3. There is good contact between the vertebral endplates and the surface of the Trial.

TIP: The pointed tip of the triangle indicates the anterior surface of the Disc Trial. Round holes in the Grabber Tips are used to align the Disc Trial in the sagittal plane.

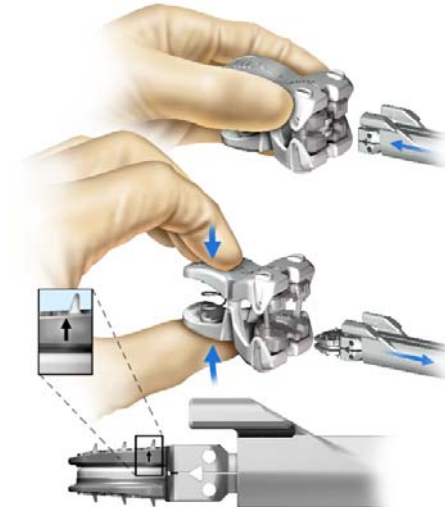
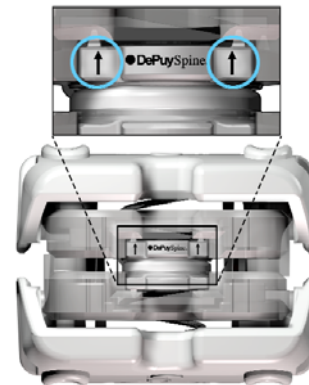
### 4. A/P Fluoroscopy Image

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



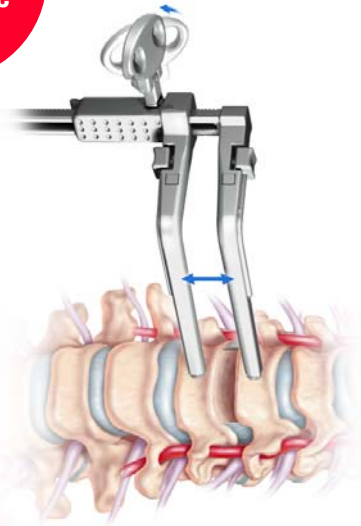
### 5. Repositioning

- The Disc Trial should be removed and another Disc Trial should be selected if:
  1. The resulting disc space height is too high or not high enough relative to adjacent levels,
  2. The centre of the Disc Trial cannot be placed at the sagittal midline 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 disc space preparation.



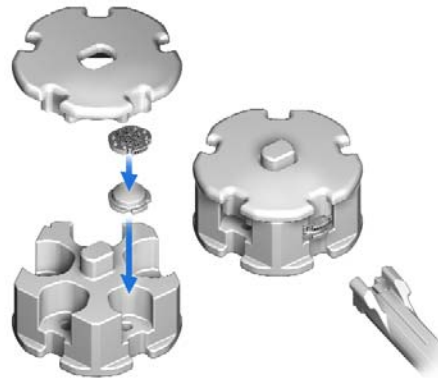
### 1. Load Implant

- The Discover™ Artificial Cervical Disc is supplied preloaded 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.
- **The surgeon must confirm the correct device orientation as indicated by the arrows on the implant pointing in the cephalad direction.**
- Select the Grabber Tip (etched with height size) that corresponds to the selected implant height and assemble with the Disc Inserter.
- Engage the implant with the Disc Inserter and then squeeze the clip to release implant.



## 2. Distraction

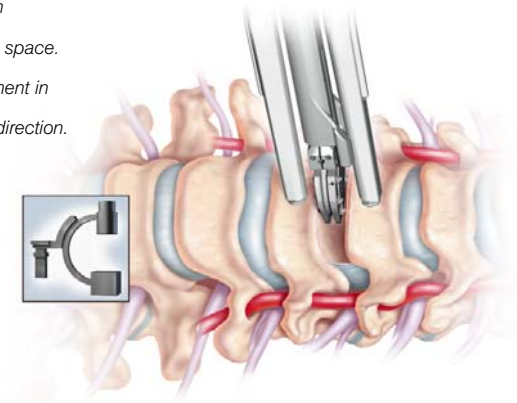
- Using the Vertebral Distractor, increase the distraction across the disc space by 2mm (one audible click on the Vertebral Distractor represents 2mm). This corresponds with the combined height of teeth on the superior and inferior endplates and will ensure that the implant can be inserted with minimal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



## 3. Implant Reloading (If Needed)

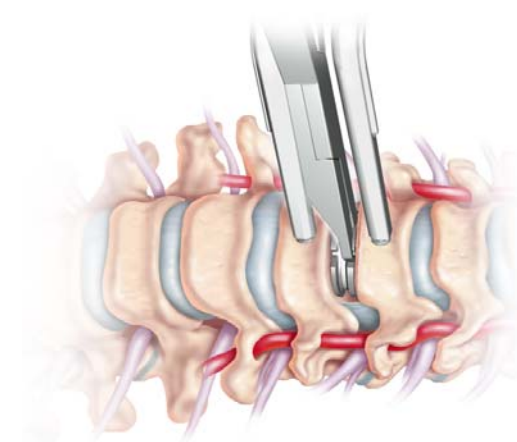
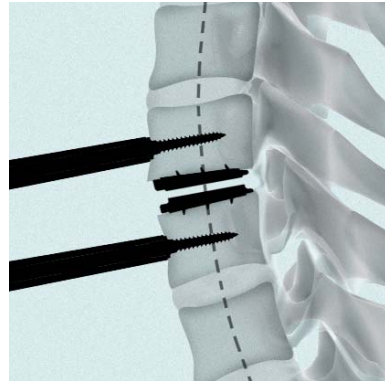
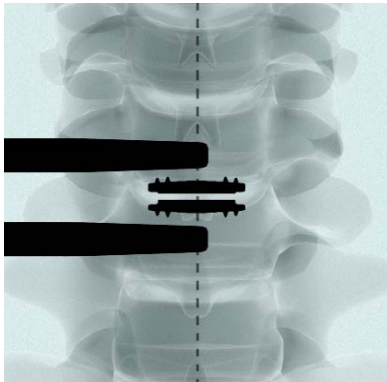
- If the implant comes loose from the clip or Grabber Tip at any point during the procedure:
  1. Ensure implant sterility has not been compromised,
  2. Check to verify articulating surfaces have not been damaged,
  3. Thoroughly rinse implant with a sterile saline solution to remove any debris,
  4. Reload the implant using the Disc Re-Loading Block.
  5. Confirm the correct device orientation as indicated by the arrows on the implant pointing in the cephalad direction.

**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.)



## 4. Implant Insertion

- Before insertion, confirm the correct device orientation as indicated by the arrows pointing in a cephalad direction.
- Insert the Discover™ Artificial Cervical Disc in the frontal midline.
- Verify that the position of the A/P Stop is the same as was pre-determined in the trialing step.
- Continually monitor the depth and progression of the implant using fluoroscopy.
- Once the Discover™ Artificial Cervical Disc has been implanted to the required depth, release the distraction applied across the Vertebral Distractor and disengage the Disc Inserter. by turning the knob on the Disc Inserter counter clockwise.



#### 5. A/P Plane Position Confirmation

- Use an A/P fluoroscopic image to confirm:
  1. Correct positioning of the device in the frontal midline.
  2. There is good apposition (i.e. no radiolucency) between the vertebral endplates and the prosthetic endplates.

#### 6. Sagittal Position Confirmation

- Use a sagittal fluoroscopic image to confirm:
  1. The device is correctly positioned at the sagittal midline of the vertebral bodies.

2. There is good apposition (i.e. no radiolucency) between the vertebral endplates and the prosthetic endplates.
  3. The “fixation teeth” are properly engaged in the vertebral bodies.
- If necessary, the Vertebral Distractor can be used to apply compression to the device to better seat the fixation teeth.

#### 7. Implant Repositioning

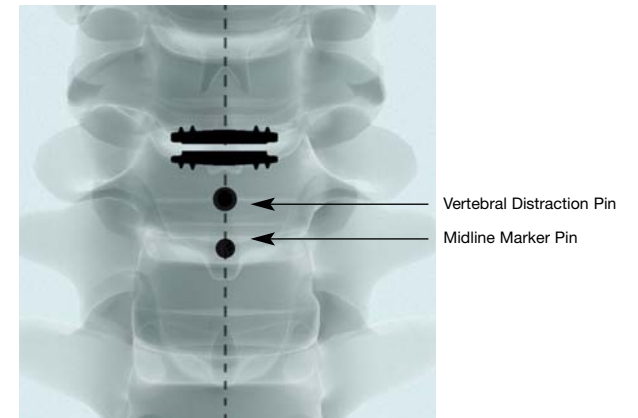
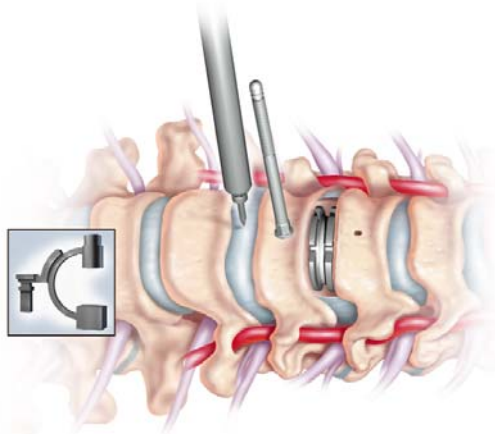
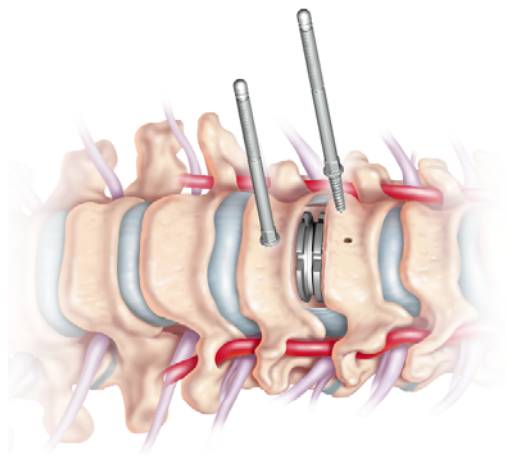
- The Discover™ Artificial Cervical Disc should be removed if:
  1. It is malpositioned in the frontal and/or sagittal planes.

2. Further endplate preparation is required to allow good apposition (i.e. no radiolucency) between the vertebral endplates and prosthetic 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 during the primary surgery, use the Disc Inserter to engage the implant and remove the assembly, then:
    1. Examine articulating surfaces to ensure they have not been damaged.
    2. Thoroughly rinse implant with a sterile saline solution to remove any debris.
    3. Reload the implant using the Disc-Re-Loading Block.

#### 8. Implant Removal

- If the implant cannot be properly engaged with the Disc Inserter, the Disc Removal Tool can be used to explant the device one endplate at a time.

**Note:** If the disc has been removed using the Disc Removal Tool, it should not be reimplanted.



### 1. Distraction Pin Placement for 2-Level Disc Implantation

**Note:** When performing a two-level procedure, pay special attention to the implant sizing to avoid overdistraction.

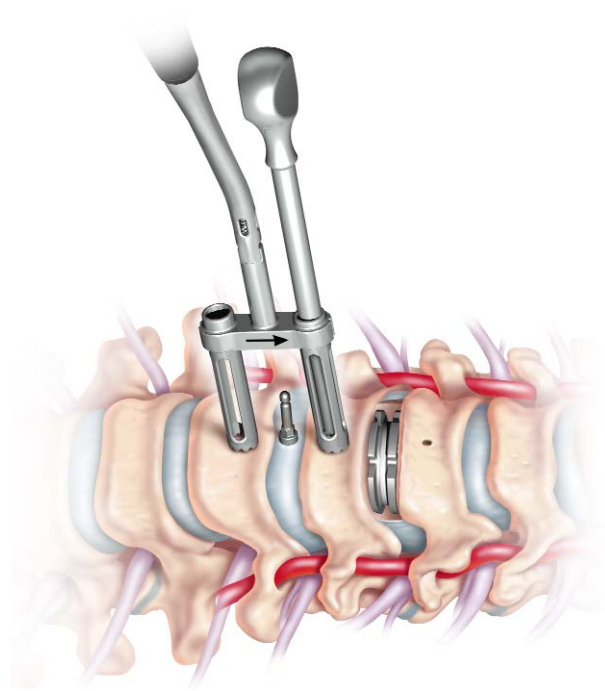
- Remove the Vertebral Distraction Pin not adjacent to the second operative level.
- Confirm the remaining Distraction Pin is securely engaged and has not loosened. If the Distraction Pin has loosened, it is recommended that it be replaced with the 3.3mm diameter Distraction Pin.

### 2. Midline Identification

- Approximate the midline using the remaining Vertebral Distraction Pin and anatomical landmarks such as the midpoint between the fibre of the longus coli muscle and/or the midpoint between the uncovertebral joints.
- Insert a Midline Marker Pin into the disc in the frontal midline.

### 3. Confirm Marker Pin is in Midline Position

- Take an A/P fluoroscopic image to confirm that the Midline Marker Pin is in the frontal midline of the vertebral bodies.



#### 4. Double Barrel Guide Selection

- Use the Double Barrel Guide, which allows placement of the Vertebral Distraction Pins in the centre of the two vertebral bodies.
- The Double Barrel Guide should be oriented so that the indicator arrow is pointing in the cephalad direction.
- The Double Barrel Guide should be placed over the remaining Vertebral Distraction Pin and aligned over the Midline Marker Pin in the previously determined midline.
- Insert the Double Barrel Guide Stabilization Sleeve over the remaining Vertebral Distraction Pin and into the Double Barrel Guide.

#### 5. Complete 2<sup>nd</sup> Level Implant

- Follow the steps for single level implantation starting at the “Awl vertebral bodies” step of the “Identify Midline” section.
- Upon completion of second level implantation, confirm alignment of both levels using A/P and sagittal fluoroscopic imaging.







